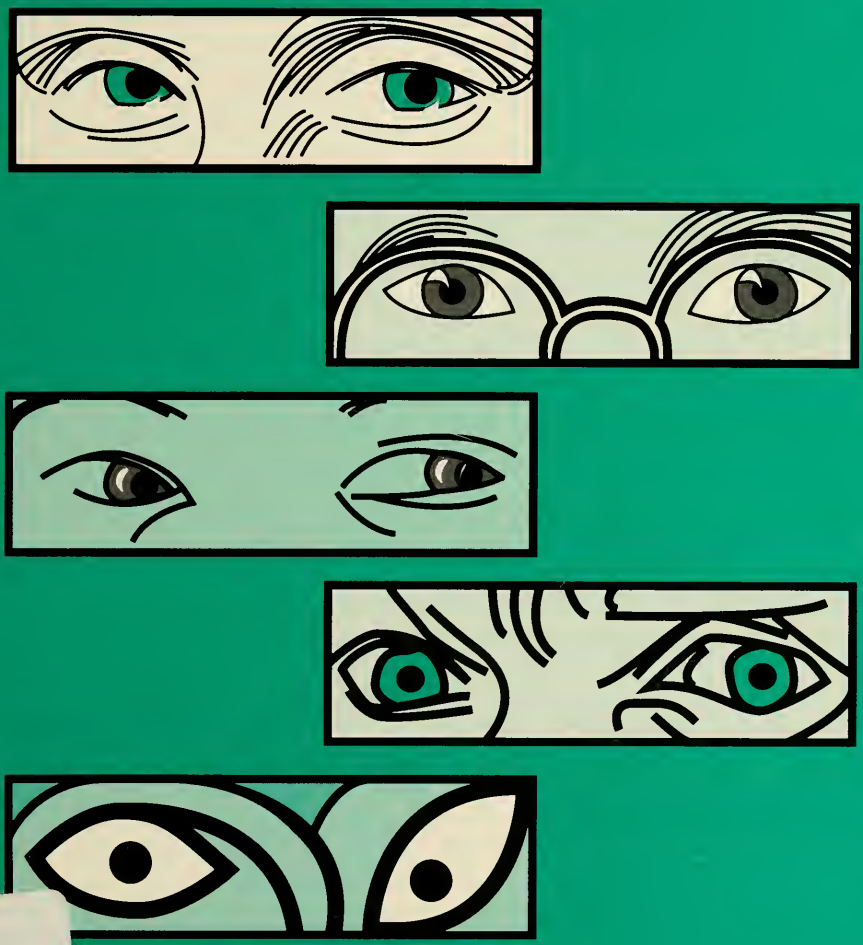
Clinical Practice Guideline

Clinical Practice Guideline
Number 4

Cataract in Adults: Management of Functional Impairment



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Cataract in Adults

The Agency for Health Care Policy and Research (AHCPR) was established in December 1989 under Public Law 101–239 (Omnibus Budget Reconciliation Act of 1989) to enhance the quality, appropriateness, and effectiveness of health care services and access to these services. AHCPR carries out its mission by conducting and supporting general health services research, including medical effectiveness research, facilitating development of clinical practice guidelines, and disseminating research findings and guidelines to health care providers, policymakers, and the public.

The legislation also established within AHCPR the Office of the Forum for Quality and Effectiveness in Health Care (the Forum). The Forum has primary responsibility for facilitating the development, periodic review, and updating of clinical practice guidelines. The guidelines will assist practitioners in the prevention, diagnosis, treatment, and management of clinical conditions.

Other components of AHCPR include the following. The Center for Medical Effectiveness Research has principal responsibility for patient outcomes research and studies of variations in clinical practice. The Center for General Health Services Extramural Research supports research on primary care, the cost and financing of health care, and access to care for underserved and rural populations. The Center for General Health Services Intramural Research uses large data sets for policy research on national health care expenditures and utilization, hospital studies, and long-term care. The Center for Research Dissemination and Liaison produces and disseminates findings from AHCPR-supported research, including guidelines, and conducts research on dissemination methods. The Office of Technology Assessment responds to requests from Federal health programs for assessment of health care technologies. The Office of Science and Data Development develops specialized data bases for patient outcomes research.

Guidelines are available in formats suitable for health care practitioners, the scientific community, educators, and consumers. AHCPR invites comments and suggestions from users for consideration in development and updating of future guidelines. Please send written comments to Director, Office of the Forum, AHCPR, Executive Office Center, Suite 401, 2101 East Jefferson Street, Rockville, MD 20852.

Clinical Practice Guideline
Number 4

Cataract in Adults: Management of Functional Impairment

Cataract Management Guideline Panel

U.S. Department of Health and Human Services
Public Health Service
Agency for Health Care Policy and Research
Rockville, Maryland

AHCPR Publication No. 93–0542
February 1993

Guideline Development and Use

Guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions. This guideline was developed by an independent, multidisciplinary panel of private sector clinicians and other experts convened by the Agency for Health Care Policy and Research (AHCPR). The panel employed an explicit, science-based methodology and expert clinical judgment to develop specific statements on patient assessment and management for the clinical condition selected.

Extensive literature searches were conducted and critical reviews and syntheses were used to evaluate empirical evidence and significant outcomes. Peer review and field review were undertaken to evaluate the validity, reliability, and utility of the guideline in clinical practice. The panel's recommendations are primarily based on the published scientific literature. When the scientific literature was incomplete or inconsistent in a particular area, the recommendations reflect the professional judgment of panel members and consultants. In some instances, there was not unanimity of opinion.

The guideline reflects the state of knowledge, current at the time of publication, on effective and appropriate care. Given the inevitable changes in the state of scientific information and technology, periodic review, updating, and revision will be done.

We believe that the AHCPR-assisted clinical guideline development process will make positive contributions to the quality of care in the United States. We encourage practitioners and patients to use the information provided in this *Clinical Practice Guideline*. The recommendations may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in light of available resources and circumstances presented by individual patients.

J. Jarrett Clinton, MD
Administrator
Agency for Health Care Policy and Research

Foreword

The development of opacities or cataracts in the lens of the eye is a normal consequence of aging and is common in persons age 60 and over. In time, the opacities may affect vision and ultimately impair quality of life. With the increased prevalence of cataract as the U.S. population ages, the care of patients with cataract has become a major component of health care delivered to all Americans. An estimated 1.35 million cataract surgeries are performed annually.

Despite major technological advances in microsurgical techniques, concerns have been raised about the appropriateness of surgery for patients with functional impairment due to cataract. There is also concern that other factors, such as race and economics, may influence access to care. For laser capsulotomy, sometimes performed after cataract surgery to treat posterior opacification, there may be a vast difference in rates of performance even between contiguous States. Such findings suggest a lack of agreement on appropriate indications for use of the procedure. This guideline is written in response to these and other uncertainties. It sets out an approach to the process of care for patients with cataract that is comprehensive, coherent, and yet flexible enough to apply to a broad range of patients who experience functional impairment as a result of the visual effects of the cataract.

This *Clinical Practice Guideline* was developed under the sponsorship of the Agency for Health Care Policy and Research (AHCPR) of the U.S. Department of Health and Human Services. To develop this guideline, AHCPR convened an interdisciplinary expert panel made up of ophthalmologists, nurses, optometrists, internists, a psychiatrist, an anesthesiologist, a generalist, a clinical social worker, and a patient representative. The panel first undertook an extensive and interdisciplinary review of the process of care for the patient. Second, the panel conducted a comprehensive review of the field to define the existing knowledge base and to evaluate critically the assumptions and common wisdom in the field. Third, the panel initiated a peer review of the guideline drafts and field review with intended users in clinical sites. Finally, comments from these reviews were assessed and used in the development of the final guideline.

This is the first edition of the *Clinical Practice Guideline* on *Cataract in Adults: Management of Functional Impairment.* The panel recognizes that issues surrounding the management of cataract are complex and controversial. A revised edition will be produced in 2 years to reflect new research findings and the experience with newer methods of management.

Cataract Management Guideline Panel

Abstract

Cataract surgery performed to redress functional impairment due to cataract in the adult is the most common surgical procedure performed on Americans age 65 and over. As a result, cataract surgery is a significant item in the Medicare budget. It is important to recognize the impact of cataract-related disability on an individual's ability to function autonomously. The goal of the guideline is to promote appropriate management of adults with functional impairment due to cataract. A distillation of a more extensive *Guideline Report*, the *Clinical Practice Guideline* serves as an easy-to-use reference for physicians and other health care providers. It consists of recommendations for providing the highest quality of care, based on an extensive review of the relevant literature and on expert opinion and panel consensus. Functional impairment due to cataract is a broad topic that includes the following considerations: ethical issues, natural history and risk factors, access to and referral for care, setting of care, preoperative tests, various aspects of surgery and preoperative management, postoperative care, rehabilitation, and YAG capsulotomy.

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Panel Members

Denis M. O'Day, MD, FACS,
Chair
George Weeks Hale Professor
and Chair
Department of Ophthalmology
Vanderbilt University
School of Medicine
Nashville, Tennessee
Ophthalmologist

Anthony J. Adams, OD, PhD
Dean
School of Optometry
University of California
Berkeley, California
Optometrist

Edwin H. Cassem, MD, FACP
Chief of Psychiatry
Department of Psychiatry
Massachusetts General Hospital
Boston, Massachusetts
Psychiatrist

John V. Donlon, Jr., MD
Acting Chairman
Department of Anesthesiology
Massachusetts Eye and Ear
Infirmary
Boston, Massachusetts
Anesthesiologist

Donald J. Doughman,
MD, FACS
Professor
Department of Ophthalmology
University of Minnesota Hospital
and Clinic
Minneapolis, Minnesota
Ophthalmologist

Dagmar B. Friedman,
MPH, LICSW
Consultant
Vision Rehabilitation Services
Massachusetts Eye and Ear
Infirmary
Beverly Farms, Massachusetts
Medical Social Worker

Catherine Glynn-Milley,
RN, CRNO
President
Specialty Nursing Agency, Inc.
Santa Clara, California
Home Health Nurse

Harry L. Knopf, MD
Associate Professor
of Clinical Ophthalmology
Department of Ophthalmology
and Visual Sciences
Washington University
School of Medicine
St. Louis, Missouri
Ophthalmologist

Ernest L. Mazzaferri,
MD, FACP
Professor and Chairman
Department of Internal Medicine
Ohio State University
College of Medicine
Columbus, Ohio
Internist

Steven A. Obstbaum, MD
Professor of Clinical
Ophthalmology
Cornell University Medical School
Director
Department of Ophthalmology
Lenox Hill Hospital
New York, New York
Ophthalmologist

Charles J. Pappas, OD
Director of Optometric Services
Bascom Palmer Eye Institute
University of Miami
School of Medicine
Miami, Florida
Optometrist

Eva N. Skinner, RN
Los Angeles, California
Patient Representative

Alfred Sommer, MD, MHS
Dean
The Johns Hopkins School
of Hygiene and Public Health
Baltimore, Maryland
Ophthalmologist

Arlo C. Terry, MD
Associate Clinical Professor
of Ophthalmology
University of Texas
San Antonio, Texas
Ophthalmologist

Linda A. Vader, RN, CRNO
Certified Registered Nurse
in Ophthalmology
University of Michigan
Kellogg Eye Center
Ann Arbor, Michigan
Nurse Manager

James R. Weber, MD
Assistant Clinical Professor
Department of Family and
Community Medicine
University of Arkansas
Jacksonville, Arkansas
Family Physician

Von Best Whitaker, PhD, RN, C
Assistant Professor
School of Nursing
University of Texas
Health Science Center
San Antonio, Texas
Nurse

Ira G. Wong, MD
Chief
Department of Ophthalmology
Kaiser Permanente Medical Center
Assistant Clinical Professor
University of California-
San Francisco
Redwood City, California
Ophthalmologist

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Earl Steinberg, MD, MPP, consultant to the panel on methodology of the literature review, participated in the development and implementation of the literature search and advised the panel throughout the process. He also participated in the literature review. Kay Dickersin, PhD, Director of the Ad Hoc Literature Review Group, maintained oversight of the entire process and consulted with the panel chair and panel members regarding reviews of individual topics. She also participated in the literature review. Lea Gamble supervised the logistics of the literature review and the distribution of the multitude of abstracts and articles to the review teams.

Paul Dokeki, PhD; Albert Jonsen, PhD; Tom Leonard-Martin, PhD; Robert O'Gorman, PhD; Edmund Pelligrino, PhD; Robert Veatch, PhD; and Richard Zaner, PhD, read and commented on drafts from the Ethics section.

Lisa Herdelin (12/91-present) and Bridget Reilly, PhD (5/91-12/91) were responsible for the overall administration of the project at Vanderbilt University School of Medicine. Lisa Herdelin also contributed to the editing of the final drafts of the documents. Susan Bigham and Sandra Wilkinson prepared drafts and revisions and were responsible for maintaining secretarial assistance to the panel.

Susan Garratt wrote drafts of the *Clinical Practice Guideline* and copyedited the *Guideline Report* and its three other versions. Robert Friedman, MD, prepared drafts of the *Quick Reference Guide.* David Hadorn, MD, developed the algorithm. Gary Stephenson and Marcia Whitson wrote drafts of the *Patient's Guide.* Naomi Levy and Charlie Smith served as production editors for the *Clinical Practice Guideline.* Maggie Rutherford of the Center for Research Dissemination and Liaison, Agency for Health Care Policy and Research (AHCPR), served as the managing editor on all guideline products.

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Executive Summary

Functional impairment due to cataract in adults was designated as a topic for guideline development for two reasons. First, it is prevalent in the U.S. population, and, second, surgery for the condition is a significant item in the Medicare budget. It is the most common surgery performed on Americans age 65 and over, with an estimated 1.35 million procedures being performed every year at a cost of approximately $3.4 billion. Despite the fact that in the United States surgery is perceived as generally available, cataract remains an important cause of visual loss in the U.S. populations surveyed.

The panel chose to focus, in general, on functional impairment of the patient with cataract and, in particular, on improvement in function as a result of treatment for the condition. Functional impairment due to cataract in the adult is a broad topic. Although the word cataract immediately raises in most minds the question of surgery, the issues addressed in this guideline are much broader. From the perspective of the body's five senses, a cataract can cause a decrease in visual function that can be classed as a visual disability. The panel believes that it is important to recognize the impact of this disability on the individual's ability to function autonomously. Maintenance or restoration of autonomy through appropriate treatment to remove the disability, therefore, becomes the goal of the guideline.

The direct link between vision, independence, and quality of life makes vision one of our most precious attributes. Improving vision for the elderly with the skills of professional providers not only is possible but also should be a high priority.

This guideline is based, first, on knowledge derived from the relevant literature and, second, on expert opinion. The process of developing the guideline involved several stages. The panel defined the scope of the guideline and the topics to be researched and initiated a systematic review of the medical literature relating to cataract. The National Library of Medicine conducted a broad-based search of the available literature, and the literature review teams synthesized the findings in this literature in a series of scientific reports that were used in developing the guideline. Other inputs into the guideline included the panel's own expertise, information from open forum presentations, peer- and pilot-review results, and informal communications with the panel chair and panel members. In the absence of empirical evidence, the panel made informed judgments and agreed on them by consensus.

The guideline consists of recommendations for the provision of the highest quality of care for patients with functional impairment due to cataract, consistent with present knowledge, together with the panel's reasoning to support these recommendations.

To facilitate a broad approach to the care of persons with functional impairment due to cataract, this guideline covers the following subjects:

- Ethical issues, which are an integral component of the delivery of health care. When guidelines are developed, they must embody the covenantal motivation; no legislative enactment or legal contract can suffice. The covenant includes numerous elements that define the role and responsibility of the caregiver.
- The natural history of cataract and functional impairment due to cataract, risk factors for cataract, which provide the basis for our understanding of the disease and its impact on the patient, and the interventions that eventually might be undertaken to prevent the formation of cataract or reduce the disability caused by it. Currently, there is no medical treatment to prevent formation and progress of cataract in the otherwise healthy adult eye. The major risk factors for cataract are ultraviolet-B radiation, certain drugs, diabetes, smoking, and alcohol. There may also be an association with severe diarrhea or low antioxidant vitamin status. At this time, however, guidelines for risk factor management cannot be provided.
- Referral pathways and access to care. It is of great importance how patients with functional impairments due to cataract come to receive care and how this process of interaction with the health care system influences the outcome for the individual. The process of caring for a patient with functional impairment due to cataract should start when a visual disability is recognized. This should lead finally to consultation with an appropriate surgeon to make or confirm a diagnosis and provide appropriate treatment.
- Setting and providers of care. Major changes that have taken place in the setting of care in the past few years and how these new settings are structured can also have a crucial impact on the outcome. The setting for surgery should be where a patient can receive quality care in a safe environment, ideally close to his or her home or support system. This may mean that a surgeon other than the one who diagnosed the cataract performs the surgery, if it is in the patient's best interest. In addition, other health care providers (e.g., optometrists, anesthesia providers, home health nurses, social workers) are currently more visibly involved in certain components of the care of these patients as part of the health care team.
- The value and suitability of a series of preoperative tests used for a variety of purposes in the management of the patient with cataract. The decision to perform cataract surgery is generally made by judging the effect of the cataract on the patient's visual and overall function and assessing the patient's visual needs, after a thorough consideration of the potential risks associated with surgery. Several specific preoperative tests are discussed.

- Various aspects of treatment, including nonsurgical management, surgical management, the indications for surgery that are to be used in defining the suitability of a patient for surgery, preoperative evaluation, anesthesia, surgical techniques and complications, and second eye surgery. Modern cataract surgery is safe and effective in restoring vision in patients with cataracts.
- Postoperative care, rehabilitation, and yttrium aluminum garnet (YAG) capsulotomy for posterior capsular opacification. The components of postoperative care include patient education, evaluation of the condition at discharge, and postoperative visits and examinations. Numerous factors are involved in successful rehabilitation, and these are discussed fully. Finally, the management of functional impairment due to posterior capsular opacification is described in a way similar to the management of functional impairment due to cataract. This includes consideration of diagnosis, indications and contraindications for surgery, preoperative evaluations, the surgical technique and complications, postoperative care, and benefits and harms. Opacification of the posterior capsule is a natural consequence of modern cataract surgery. Now, with the availability of the YAG laser, it is possible to perform laser capsulotomy as an outpatient surgical procedure after cataract surgery.

1 Overview

Guideline Development Process

The Agency for Health Care Policy and Research (AHCPR) was established on December 19, 1989, by the Omnibus Budget Reconciliation Act (Public Law 101-239) as one of the agencies of the Public Health Service. The purpose of AHCPR is to enhance the quality, appropriateness, and effectiveness of health care services and access to such services. As specified by Section 911 of the Act, the Office of the Forum on Quality and Effectiveness in Health Care was established within AHCPR. The Forum was directed to facilitate the development and periodic review and updating of:

> *Clinically relevant guidelines that may be used by physicians, nurses, social workers, educators, and health care practitioners to assist in determining how diseases, disorders, and other health care conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically. (Section 912)*

The legislation that established AHCPR mandated that guidelines on at least three clinical conditions be completed and submitted to Congress by January 1, 1991, and that a report evaluating the effects of these guidelines be submitted to Congress in 1993. The selection by AHCPR of clinical conditions for guideline development is to be based on the following considerations:

- Adequacy of scientific evidence related to a topic.
- Prevalence of the clinical condition.
- Morbidity and mortality associated with the condition.
- Possibility for prevention of the condition.
- Potential for benefit.
- Variability in practice.
- Importance of the condition to the Medicare and Medicaid populations.
- Costs of the condition to patients and other payers.

Guidelines are developed by panels of qualified experts and health care consumers convened by AHCPR. Panel chairs are selected from nominations submitted to AHCPR by interested organizations of health care practitioners. Panel members are selected from nominations encompassing a broad range of interested organizations and individuals, including health care professional societies and consumer organizations. The American Academy of Ophthalmology has demonstrated the feasibility of developing such a guideline with the publication of "Cataract in the Otherwise Healthy Adult Eye" in its *Preferred Practice Pattern* series.

General methods for guideline development have been specified by AHCPR. They require that "all scientific evidence is considered, the consequences of different options are weighed, and the scientific evidence and subjective judgments supporting the chosen options are described explicitly." Although it is intended that the guidelines will rely on scientific evidence as much as possible, it is also recognized that professional judgment and group consensus may also be used during the process when insufficient empirical evidence is available to evaluate the safety or effectiveness of treatments or procedures. The guidelines must be explicit as to when conclusions are derived from evidence and when professional judgments are being made. In addition to summarizing the available evidence, panels are expected to identify areas where additional research is needed.

The process of developing a guideline based, first, on knowledge derived from the relevant literature and, second, on expert opinion involved several stages. The panel convened by AHCPR to study cataract was provided with the general topic for guideline development. The specific issues to be addressed were subsequently defined by the panel at its initial meeting. In consultation with the Ad Hoc Literature Review Group, the guideline panel identified the scope of the guideline and the topics to be researched in the literature review. The panel chose to focus, in general, on functional impairment of the patient with cataract and, in particular, on improvement in function as a result of treatment for the condition.

After consultation with the director of the literature review, the methodology consultant, and panel members, the panel chair appointed literature review teams for each topic. These teams consisted of content and methodology experts, content and methodology form developers, and literature reviewers. In order to meet the charge to consider all scientific evidence, the panel initiated a systematic review of the medical literature relating to cataract. The specific methods used in this review are described in detail in this chapter's methodology section and in Appendix A of the *Guideline Report*. In general, the National Library of Medicine planned the literature search, with ad hoc notification of additional articles by the panel members and medical community also included in the plan in order to maximize ascertainment of all available data. The literature review teams prepared the results in a series of scientific reports (see the appendices in the *Guideline Report*), which were submitted to the panel to assist in the guideline development. The panel wrote and approved the guideline, using as resources the report of the literature review, its own expertise in the areas under consideration, and information obtained as a result of presentations made to open forums as well as informal communications with the panel chair and panel members. Methods used in the guideline development, including the literature review portion, are comparable across all AHCPR-sponsored guideline panels.

As noted earlier, when empirical evidence was not available for a particular question posed by the cataract guideline panel, panel members made informed judgments and agreed on them using the consensus process. Thus, although scientific evidence from the literature was the primary source for the conclusions drawn by the panel in writing the guideline, it was not the only source. Consideration of the opinions of the experts on the panel was necessitated not only by the absence of published data regarding specific issues, but also by the fact that, in some instances, the results available in the published literature are based on clinical practices and surgical techniques that have since been updated by other approaches and are infrequently or no longer practiced. The basis for conclusions presented herein will be stated as required. The guidelines developed by each panel are dynamic documents. As with any review of available evidence, they are necessarily at risk of being outdated by the time they are published. AHCPR plans to review the guidelines at regular intervals and to update them when significant advances warrant.

Organization of the *Clinical Practice Guideline*

Functional impairment due to cataract in adults is a broad topic. The condition is of particular importance for two reasons. First, it is prevalent in the U.S. population, and, second, surgery for the condition is a significant item in the Medicare budget. It is the most commonly performed surgery in the elderly population, with an estimated 1.35 million procedures being performed every year (Health Care Financing Administration, 1990, 1991).

Functional impairment due to cataract refers to lost or diminished ability to do any of the following:

- Perform everyday activities—bathing, dressing, eating, using the toilet, walking, preparing meals, doing housework, doing laundry, shopping, taking medicine, getting around outside, driving or using other transportation, managing money, and using the telephone.
- Participate in hobbies or other leisure-time activities (e.g., reading, watching television).
- Work in one's occupation.

Although the word cataract immediately raises in most minds the question of surgery, the issues addressed in this guideline are much broader. From the perspective of the body's five senses, a cataract can cause a decrease in visual function that can be classed as a visual disability. It is important to recognize the impact of this disability on the individual's ability to function autonomously and to perceive self as healthy. Maintenance or restoration of autonomy through appropriate treatment to remove the disability therefore becomes the goal of the guideline.

To facilitate this broad approach to the care of persons with functional impairment due to cataract, this guideline is divided into sections. The next three sections of this overview cover ethics, the natural history of cataract and functional impairment due to cataract, and risk factors for cataract. Ethical issues are an integral component of the delivery of health care. In 1983, the President's Commission for the Study of Ethical Problems in Medicine stressed the need for ethical issues to receive consideration in the formation of health care policy (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1983). The sections on the natural history of cataract and functional impairment and risk factors provide the basis for our understanding of the disease and its impact on the patient and discuss the interventions that eventually might be undertaken to deal with preventable causes. They are intended to be used as background information for the reader and were not written under the same rigorous constraints of literature inclusion criteria and review as the remaining sections. (See Appendix A in the *Guideline Report* and this chapter's methodology section.)

The second chapter of this report discusses referral pathways and access to care. Access to care has also been deemed a critical issue by the President's Commission, which wrote: "In examining the special nature of health care, we discern in our country traditional commitment to fairness and ethical obligation that all Americans have access to an adequate level of health care without the imposition of excessive burden" (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1983). In the context of the current debate, access to care remains a critical issue 9 years after this report.

The third chapter addresses changes in the setting of care for cataract and how these new settings and organizations can have a crucial impact on the outcome of the patient's encounter with the health care system. Cataract surgery has undergone a major transformation in the past few years, having been transferred almost entirely to the outpatient setting. This has been coupled with incredible technological advances in surgical techniques. In addition, other health care providers (e.g., optometrists, anesthesia providers, home health nurses, social workers) are more visibly involved in certain components of the care of these patients as part of the health care team.

The fourth chapter examines the suitability and applicability of a series of preoperative tests used for a variety of purposes in management of the patient with cataract.

The fifth chapter discusses various aspects of nonsurgical treatment and surgery, including the indications for surgery that are to be used in defining the suitability of a patient for surgery. It also contains sections on preoperative evaluation, anesthesia, surgical management and complications, and surgery on the second eye. Each of these deals separately with important aspects of the surgical management of cataracts

and provides a guideline, as far as is known, for the most appropriate way to approach patients progressing toward and having surgery.

The sixth chapter deals with postoperative care and its components. The seventh chapter deals with the issue of rehabilitation and the numerous factors that are involved in successful rehabilitation. The eighth discusses the management of functional impairment due to posterior capsular opacification (PCO) and the indications for and performance of Nd:YAG capsulotomy for PCO. YAG laser capsulotomy is the most commonly used technique for treating PCO. Nd and YAG are abbreviations that stand for neodymium and yttrium aluminum garnet.

It will become apparent on perusal of this guideline that many of the important questions raised and subjected to literature search have no ready answers. This does not necessarily mean that the practices currently followed in the United States are of poor or inferior quality. Rather, in many instances, it means that the topic has not been studied in a formal way. When the topic is of sufficient importance, and as yet not settled, the panel recommends that research be undertaken to provide scientifically definitive answers to resolve the issue. The organization of the *Clinical Practice Guideline* is designed to facilitate revision as new information comes to hand.

Ethics: The Relationship Between Caregiver and Patient[1]

As used here, the term "appropriate ethical conduct" refers to conduct within the social relationships between lay people and health professionals that is built on complex layers of trust. The bond between caregiver and patient is, therefore, a special one, to be regarded as a covenant rather than a contract. A covenant is considered inherent to the caregiving role. It exists independently of, and effectively predates, individual relationships with patients. The principal goal of this bond of trust is beneficence—acting always in the patient's best interests (whether to improve health, to relieve suffering, or merely to provide comfort). These interests are determined by ongoing discussions with the patient in the context of medical diagnosis, available therapies, and the caregiver's reasonable judgment. The bond is also expressive of certain primary professional virtues, including loyalty, fidelity, confidentiality, respect, and charity—virtues that are expected of the caregiver in all professional dealings with patients. When a person with impaired vision requests or needs help, the covenant requires that these needs be met with competence and compassion.

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[1]Prepared by Edwin Cassem, MD, FACP, and Denis O'Day, MD, FACS.

Despite the emphasis on beneficence as essential to the motivation of the caregiver, this covenant should not be construed as imposing passivity on the patient or encouraging an attitude of condescension in the caregiver. Rather, the relationship is one of interdependence. The patient, though of diminished autonomy as a result of the illness, nonetheless has authority in the relationship. This authority arises by virtue of the patient's experience of the illness that is unique and essential to the diagnosis and treatment and by virtue of the contribution to the caregiver's and society's developing knowledge of the condition. This mutual partnership demands that the caregiver listen to and honor the experience of the patient.

When guidelines are developed, therefore, they must embody the covenantal motivation; no legislative enactment or legal contract can suffice. Caregivers are bound to the communities they serve by responsibilities inherent to the service role. Moreover, in such a covenant, the individual's and the community's needs must be carefully balanced, keeping in mind that the individual's welfare takes priority and must therefore be protected from extraneous appeals to social welfare and societal concerns. At the same time, attention should be given to providing sensitive and effective care at reasonable cost. Although there are limits on what individuals can demand, it is reasonable to propose that it would be ethically unacceptable to ration cataract treatment so that some individuals in valid need of surgery would be excluded.

The overall goal for the health care professionals is to provide quality eye care to every person needing it, such that every person in valid need would be able to receive both cataract extraction and intraocular lens (IOL) implantation when indicated and the appropriate required aftercare.

For each caregiver, the covenant with the patient includes the following elements:

- Effective and sensitive communication—including skillful talking with patients and listening to the concerns of each patient.
- Appropriate education about the nature of the impairment, the proper treatment and alternatives, the prognosis, risks and benefits, and understandable rationales and explanations of needed tests and their respective results.
- Intervention at the proper level of competence.
- Continuity of care, including coverage 24 hours a day, 7 days a week, when needed, with adequate mechanisms for instructions to the patient on how to obtain care.
- Appropriate consultation with and referral to other ophthalmologists, optometrists, opticians, low-vision specialists, etc.
- On request of the patient, a full and accurate rendering of the patient's records.
- Timely and effective review of the results of consultation and laboratory tests, along with any appropriate action required.

- For all patients, and perhaps especially those who do not respond to treatment, provision of support, counseling, rehabilitative and social services, and other appropriate referrals. Preoperative assessment must identify the patient's aftercare needs and any particular obstacle to a successful outcome that would require special attention or referral.

While an attempt is being made to provide care at reasonable cost, priority must be given to quality eye care for all patients. Caregiver responsibility means that the commitment to care comes before provider convenience or costs. The first, or intrinsic, good is better visual functioning for the patient, but other goods are also achieved. Caregivers who meet the covenant responsibilities described herein earn and deserve reasonable compensation; beneficence does not preclude appropriate, competent, and reasonably compensated cataract surgery. New discoveries advance the understanding of cataract formation, leading to improved diagnosis and new ways to prevent their development. All such outcomes are welcomed and promote quality patient care and can issue from the first, intrinsic good of improving the patient's vision.

In this context, the panel was concerned by reports of some eye care providers using high-powered marketing to recruit patients who might not need cataract surgery and of ophthalmologists who do not spend appropriate time in evaluating the patient preoperatively, explain the potential risks and benefits of surgery, or assume appropriate responsibility for their postoperative care. Such conduct violates the standard of cataract care in both letter and spirit.

Protection and/or restoration of good vision for the elderly is a shared provider goal. It can make the difference for walking or driving safely, staying in touch through reading or watching television, retaining the ability to keep one's own books and to write, and enjoying the subtleties of communication with family and friends. The direct link between vision and independence and quality of life makes it one of our most precious attributes. Improving vision for the elderly is not only possible with the skills of professional providers but of the highest priority.

Natural History of Cataracts: The Relationship to Functional Impairment[2]

Cataract remains the leading cause of blindness worldwide, with an estimated 17 million blind (Foster and Johnson, 1990). The burden of this avoidable cause of vision loss falls primarily in less developed countries, where less than 20 percent of cataract patients are estimated to receive surgery (Kupfer, 1984). In the United States, surgery is perceived as generally available, and cataract surgery is the most common surgical procedure performed under Medicare. Nevertheless, cataract remains an important cause of visual loss in U.S. populations surveyed for causes of blindness (Dana, Tielsch, Enger et al., 1990; Sommer, Tielsch, Katz et al., 1991).

As the U.S. population ages, there is an urgent need to develop plans for the provision of eye care services to manage the increasing numbers of age-related eye diseases, yet there are few data on incidence or natural history of cataract. Such data are vital for health planners, for clinical trials of potential anticataract agents, and for trials on the modification or prevention of factors that may increase the risk of cataracts.

Definition of Cataract

One significant problem in reviewing existing data is the varying definitions of "cataract" that are used in the literature. Different definitions are appropriate and depend on the research or program question that is being addressed. For epidemiologic studies of risk factors, it is important to identify the earliest lens changes that represent onset of disease. Thus, one definition of cataract is the presence of lens opacities. These lens opacities are objective changes and, as such, can be evaluated and recorded, and they may or may not have associated visual impairment or functional consequences (Adamsons, Muñoz, Enger et al., 1991; Chylack, Leske, Sperduto et al., 1988; Leske, Chylack, Sperduto et al., 1988; West, Rosenthal, Newland et al., 1988). Thus, this definition may not be useful for addressing the visual or functional consequences of cataract.

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[2]This section on the natural history of cataracts was prepared by Sheila West, PhD, and contains findings from the panel's literature review. The specific literature review search questions for this category were:

Question 1. What is the natural history of idiopathic cataract, including demographics, rate of progression, impact on quality of life, and complication rates if untreated?
Question 2. What is known of epidemiology, including prevalence?
Question 3. What is known of risk factors and opportunities for minimizing the risk of developing cataract?

See the methodology section for more information on the literature review.

A second definition frequently used is a lens opacity that causes, or is accompanied by, loss of visual acuity (Adamsons, Muñoz, Enger et al., 1991; Hiller, Sperduto, and Ederer, 1983; Kahn, Leibowitz, Ganley et al., 1977). This definition has been used in prevalence surveys to identify lens opacities that are severe enough to interfere with vision. A problem with this definition is that other causes of visual acuity loss besides (or in addition to) the lens opacity must be excluded. Moreover, advanced lens changes, particularly cortical changes, can be present with no accompanying loss of acuity. Nevertheless, if data are needed on visually significant cataract, some component of loss of visual function must be included in the definition. The level of visual acuity loss may be modest (in Framingham, best visual acuity of 20/30 or worse was selected as a cutoff [Kahn, Leibowitz, Ganley et al., 1977]). However, current discussions in the ophthalmic literature report that visual acuity may not be the only appropriate vision function parameter to measure in cataract, with loss of contrast sensitivity and glare representing visual consequences more sensitive to cataractous change (Drummond, 1990).

A third dimension of cataract relates to the functional consequences of lens opacification for everyday activities. Clinicians are well aware of patients with 20/40 cataracts who report no functional disability associated with their ocular status, although other patients with seemingly good vision have curtailed driving activities. The focus of this document is the care of the patient with functional disability due to cataract.

Each of these different approaches to the definition of lens opacity or cataract has relevance in the context of the research or program focus in which it is used. However, when attempting to describe the "natural history" of cataracts, one must be precise in the definition of cataract and be aware that the implication of using any one definition will alter the epidemiologic picture. Moreover, there will also be large differences in the epidemiology of the different cataract types.

Prevalence Data

Population-based data on prevalence of cataract in the United States are few. Three sources that will be reviewed are the Framingham Eye Study, the National Health and Nutrition Examination Survey, and the Watermen Study.

The prevalence of lens opacity and cataract was determined in the Framingham Eye Study during eye examinations carried out from 1973 to 1975 (Kahn, Leibowitz, Ganley et al., 1977; Sperduto and Seigel, 1980). For determination of cataract, the definition specified lens opacities accompanied by visual acuity of 20/30 or worse. Aphakics were included in both lens opacities and cataract groups. Table 1-1 shows that age-related lens opacities were already present in 42 percent of those aged 52-64, although only 5 percent had visual impairment. By age 75-85, almost all

Table 1-1. Percent of Persons with Lens Opacity and Cataract Based on Different Surveys, by Age

Source	<35	35-44	45-54	55-64[1]	65-74	75-84[1]	85+
Framingham[1] (Source: Kahn, Leibowitz, Ganley et al., 1977)							
Lens opacities	-	-	-	41.7	73.2	91.1	-
Cataract	-	-	-	4.5	18.0	45.9	-
NHANES[2] (Source: Leske and Sperduto, 1983)							
Lens opacities	-	-	12.2	27.6	57.6	-	-
Cataract	-	-	2.6	10.0	28.5	-	-
Watermen[3] (Source: Taylor, West, Rosenthal et al., 1988)							
Lens opacities	1.8	2.7	5.7	37.0	72.1	94.2	100.0
Cataract	-	-	-	5	25	59	-

[1]Both sexes combined. Population ranged from age 52 to 85, so those age 85 are included in last grouping, and those age 52-54 are among the 55-64 group; white residents only.
[2]Both sexes and all races combined.
[3]Men only. Population ranged from age 30 to 94. Only those age 50-85 were studied for cataracts, defined as lens opacities accompanied by visual acuity of 20/30 or worse.

the population had some opacities, and nearly half either had some visual loss or were aphakic.

The National Health and Nutrition Examination Survey (NHANES) was conducted on a probability sample of the U.S. civilian noninstitutionalized population. The examinations were conducted by 91 ophthalmology residents scattered across the country, so estimates of lens opacities must be interpreted with caution, as standardization was exceedingly difficult. Cataracts were defined in NHANES as lens opacities accompanied by visual acuity of 20/25 or worse (see Table 1-1). The higher proportion found to have cataract in NHANES compared with the Framingham study may be due to higher visual loss criteria in Framingham, regional differences in NHANES, or differences in diagnosis (Leske and Sperduto, 1983). The last reason may well explain the significant differences in lens opacities between the two studies.

In 1984-85, clinical and photographic assessment of the lens was performed on 831 fishermen, or "watermen," in Maryland (Taylor, West, Rosenthal et al., 1988). Although this was not strictly a population sample but rather an occupational sample, in most of the small fishing communities visited, all the men were enrolled in the study by virtue of their occupation. The lens opacity rates and cataract prevalence were not dissimilar from those found in the previous studies (see Table 1-1), despite differences in methodology of assessment. Cataracts associated with visual impairment become prevalent after age 60-65.

In summary, although lens opacities are often found in those under age 45, there are no prevalence data on functional cataract to compare with the data on lens opacities or early cataract.

There are few data on the population-based prevalence of specific subtypes of cataract. Data from the Framingham Eye Study included information on specific subtypes of lens opacities, although 65 aphakic subjects were not included because the subtype was unknown (Sperduto and Hiller, 1984). Many of these may have been posterior subcapsular (PSC) cataract opacities. Although they are rare in population surveys, they are disproportionately represented in surgical series (Adamsons, Muñoz, Enger et al., 1991). As shown in Table 1-2, nuclear opacification was the most frequent opacity recorded, either as pure or mixed opacity. Data from NHANES also included subtype of cataract, although the number of examiners and lack of standardization in this study are serious limitations to the interpretation of findings on subtype (Hiller, Sperduto, and Ederer, 1986). No age-specific data have been published from this source, but over the entire population, nuclear cataract, alone or in combination, was the most common type. The same pattern of subtypes was observed in the watermen population, where nuclear was the most common type, except after age 80, when mixed opacities predominated (Adamsons, Muñoz, Enger et al., 1991).

The contrast with the types of cataract that actually present for surgery is interesting, in that among the younger ages, PSC was the predominant cataract type (Adamsons, Muñoz, Enger et al., 1991). Most of the mixed cases, at least in this series, also included PSC, suggesting that PSC is a significant cause of functional cataract, if not a prevalent one.

Incidence and Progression

Understanding the natural history of lens opacities and cataract will depend on knowledge of the incidence of lens opacities and progression of opacities to cataracts in the population. Such data are currently unavailable, although some longitudinal studies are now under way. Clearly, there is a need to acquire data on age-specific incidence of cataract, especially functionally significant cataract, for purposes of planning eye care delivery for the older population in the United States and other countries. The sparse data that are available and summarized here are based on statistical projections of population studies, prospective evaluations of ill-defined case series that used untested methodologies, and abstracts from meetings reporting current approaches.

Based on the Framingham Eye Study prevalence data, Podgor and associates (Podgor, Leske, and Ederer, 1983) constructed age-specific incidence estimates for lens opacities and cataracts (Table 1-3). The authors note the possibility that the incidence data for cataracts are underestimates because the definition of the cataract included the constraint that the cataract must entirely account for vision loss to 20/30 or worse.

Table 1-2. Percent of Persons with Cataract Types Based on Different Prevalence Surveys, by Age

Source	Nuclear	Cortical	PSC	Mixed
Framingham[1] (Source: Sperduto and Hiller, 1984)				
<35	-	-	-	-
35-44	-	-	-	-
45-54	-	-	-	-
55-64	5.7	4.6	2.2	5.4
65-74	18.9	9.9	2.4	17.9
75-84	30.0	5.8	1.3	36.5
85+	-	-	-	-
Watermen[1] (Source: Adamsons, Muñoz, Enger et al., 1991)				
30-39	0	<1	<1	<1
40-49	4.1	0	0	0
50-59	11.5	3.6	<1	2.4
60-69	33.0	7.4	0	15.3
70-79	45.7	7.6	0	33.3
80+	38.9	5.6	0	55.6
Surgical Series[2] (Source: Adamsons, Muñoz, Enger et al., 1991)				
<50	5.6	0	77.8	16.7
50-59	16.1	3.0	45.2	35.5
60-69	12.2	12.2	31.7	43.9
70-79	35.1	7.0	5.3	52.6
80+	19.4	8.3	8.3	63.9

[1]Data are for lens opacities.
[2]Data are based on a series of 183 cataract surgery patients.

Table 1-3. Age-Specific 5-Year Incidence of Lens Opacities and Cataracts: Framingham Eye Study

Age	Lens Opacities (Percent)	Cataracts (Percent)
55	10	1
60	16	2
65	23	5
70	31	9
75	37	15

Source: Podgor, Leske, and Ederer, 1983.

Thus, the prevalence estimates, which are the starting parameters in the model, may not include cataracts that occurred in combination with other diseases that may also contribute to visual loss. Although an estimated 10-37 percent of the population may develop early lens opacities, the incidence of visually impairing cataract is lower, according to this model.

When Podgor's methodology is applied to the Watermen prevalence data, the incidence of specific types of opacities can be calculated. The incidence for cortical and nuclear opacities within comparable age groups is equal to or slightly higher than the incidence of total lens opacity in the Framingham data (Table 1-4). In both populations, the incidence appears to increase with age, with some suggestion of leveling off in the oldest age group (see Table 1-4). Clearly, actual longitudinal data are needed in populations before conclusions on incidence can be drawn.

Table 1-4. Age-Specific Incidence of Cortical or Nuclear Lens Opacities: Watermen Eye Study[1]

Age	Cortical (Percent)	Nuclear (Percent)
30-39	1	<1
40-49	3	2
50-59	8	12
60-69	17	32
70-79	32	51
80+	32	55

[1]The opacities are not mutually exclusive.
Source: S. West, personal communication.

Conclusions

There is a significant need for a sensitive and reliable system to detect cataract change for longitudinal studies (Muñoz, West, Wang et al., 1991). Several methods have been proposed, and all are prone to measurement error, which in some cases can result in equal amounts of "improvement" and progression. Data from case series suggest that progression rates of opacities may be higher than the incidence of new opacities (Chylack, Leske, Khu et al., 1989; Magno, Datiles, Sperduto et al., 1991). This observation needs to be studied in population series to confirm the validity.

More information on incidence and progression will be generated from currently funded research projects on risk factors for lens opacities. However, few of the current studies are designed to evaluate the incidence of cataracts that cause functional disability or to determine the progression of cataracts from having no functional consequences to those causing functional loss. This research is clearly necessary to evaluate the likely onset of functional loss from lens opacities and the probable need for cataract surgery in the future.

Such studies are difficult to undertake for at least two reasons. First, instruments to measure the functional impact of cataracts are in the developmental stage. Many instruments on functional status do not include measures likely to be affected by decreases in vision or glare. Special instruments designed to assess specific functional loss attributable to vision

have not been completely validated. Additionally, comorbid conditions among those with cataract need to be assessed, as a decrease in vision may be exacerbated by the presence of other diseases to produce functional loss; conversely, any benefit from surgery may be mitigated by the presence of other conditions (Elam, Graney, Applegate et al., 1988). Despite these difficulties, there is growing recognition by policymakers that functional outcome and quality-of-life issues are important determinants of health care policy priorities (Drummond, 1990).

Prevention and Risk Factors

Approaches to cataract control have centered on the timely and cost-efficient provision of surgical services to those most in need (Taylor and Sommer, 1990). However, if risk factors for cataracts could be identified and strategies for prevention implemented, the volume of cataract blindness would diminish. For example, it has been estimated that if a factor could be found that simply delayed the onset of cataract by 10 years, the number of cataract operations would decline by 45 percent (Kupfer, 1984). The purpose of this review is to summarize the data on known risk factors for cataract.

Ultraviolet-B Radiation

A number of ecologic studies have shown a higher prevalence of cataracts or lens opacities in populations living in areas with high ultraviolet-B (UV-B) radiation (Brilliant, Grasset, Pokhrel et al., 1983; Hiller, Sperduto, and Ederer, 1983; Hollows and Moran, 1981; Taylor, 1980). The consistency of the association despite different populations and study methodologies strengthens the likelihood that UV-B is a causal factor. Recent studies using measures of personal exposure to UV-B have shown that cortical opacities and PSC opacities are related to cumulative lifetime exposure to UV-B (Bochow, West, Azar et al., 1989; Taylor, West, Rosenthal et al., 1988). These studies have also shown the important effect of sunglasses and hat use in reducing ocular exposure to UV-B. However, because the amount of risk attributable to UV exposure is unknown, it is not possible to estimate the effect of such protection on the likelihood of developing a cataract that will require cataract surgery.

Diabetes

Diabetics appear to be at higher risk for cataract compared with nondiabetics (Ederer, Hiller, and Taylor, 1981). The excess mortality associated with cataract patients is confined to those with diabetes (Podgor, Cassel, and Kannel, 1985), and diabetics with cataracts appear to be at greater risk of death than those without cataracts (Cohen, Neil, Sparrow et al., 1990). The mechanism of action for "sugar cataracts" was described in

several reviews (Kinoshita, 1990; Kinoshita, Fukushi, Kador et al., 1979). PSC, cortical, and mixed opacities were the types most commonly associated with diabetes in case-control studies (Bochow, West, Azar et al., 1989; Leske, Chylack, and Wu, 1991).

Drugs

Several drugs have been proposed as potentially cataractogenic, although detailed studies are few. The association between corticosteroid use and risk of PSC cataract is well known (Black, Oglesby, von Sallman et al., 1960; Bochow, West, Azar et al., 1989; Italian-American Cataract Study Group, 1991; Leske, Chylack, and Wu, 1991), although controversy remains over the role of individual susceptibility and dose or duration of steroid therapy. The possible protective effect of aspirin was not confirmed by data from several studies (Peto, Gray, Collins et al., 1988; Seddon, Christen, Manson et al., 1991; Seigel, Sperduto, and Ferris, 1982; West, Muñoz, Newland et al., 1987). It is unlikely that aspirin in prophylactic or sporadic doses is protective against cataract formation.

Diuretics have been implicated in cataractogenesis (Clayton, Cuthbert, Seth et al., 1984; Klein, Klein, and Moss, 1985; Mele, Alston, Moorman et al., 1990). However, it is difficult to disentangle the effect of the diseases for which these drugs are prescribed from the effect of the drugs themselves. In one study with longitudinal data on thiazide use, the risk of cortical opacities was highest in individuals using thiazides for 4 or more years, but they also had hypertension of long duration (Mele, Alston, Moorman et al., 1990).

Major tranquilizers, particularly phenothiazines such as chlorpromazine, were associated with increased risk of cataract (Clayton, Cuthbert, Seth et al., 1984; Collman, Shore, Shy et al., 1988). Another study with longitudinal data on phenothiazine use was equivocal, with no evidence of a dose-response relationship with cataract extraction (Isaac, Walker, Jick et al., 1991). Patients with decreased vision, including vision loss from cataract, are known to be depressed (Elam, Graney, Applegate et al., 1988). Association of the use of these drugs in the recent past with cataracts (particularly with cataract extraction) may be more reflective of the depressive consequence of vision loss.

Smoking

Risk of nuclear opacities from smoking was first reported in 1989 (West, Muñoz, Emmett et al., 1989) and was confirmed in other studies (Christen, Manson, Seddon et al., 1992; Flaye, Sullivan, Cullinan et al., 1989; Hankinson, Willett, Colditz et al., 1992; Leske, Chylack, and Wu, 1991). In addition, there may well be an increased risk of developing PSC cataract (Christen, Manson, Seddon et al., 1992; Hankinson, Willett,

Colditz et al., 1992). Exsmokers appeared to have a lower risk than current smokers, regardless of amount smoked.

Diarrhea

Another factor of potential importance is the possible effect of severe diarrheal episodes on cataractogenesis. This may be of greater relevance in countries where diarrhea is endemic and more severe than in the United States. The data, however, are conflicting: one study found a 21-fold increased risk of cataract associated with two or more episodes of severe diarrhea (Minassian, Mehra, and Jones, 1984); several other studies have found no association (Bhatnagar, West, Vitale et al., 1991; Mohan, Sperduto, Angra et al., 1989).

Alcohol

Several studies have now reported an association between heavy drinking and cataracts (Clayton, Cuthbert, Duffy et al., 1982; Harding and van Heyningen, 1989; Muñoz, West, Tajchman et al., forthcoming; van Heyningen and Harding, 1988). One study found a fourfold increased risk of PSC cataract in those who were consuming one drink per day on average. As alcohol consumption is fairly ubiquitous worldwide, this hypothesis deserves further investigation in other settings.

Antioxidant Vitamins

Nutritional status and cataracts present a complex and confusing picture. The data from human studies are sparse and incomplete. One problem is the high correlation among dietary intakes of various nutrients. For example, early work in India suggested diets low in protein may be a risk factor for cataract; however, these diets may be low in a number of micronutrients (such as riboflavin) as well (Chatterjee, Milton, and Thyle, 1982).

Current studies are suggestive of an increased risk of cataract associated with low antioxidant status (Jacques, Chylack, McGandy et al., 1988; Jacques, Hartz, Chylack et al., 1988; Leske, Chylack, and Wu, 1991; Vitale, West, Hallfrisch et al., 1991). However, the type of cataract associated with low antioxidant status varies from study to study, and the constituents of the "antioxidant indices" vary, making the results of this body of work inconclusive. It is premature to recommend vitamin ingestion as a control strategy until further research is more definitive (West, 1991).

Conclusions

The last 5 years have produced a wealth of data on risk factors for cataracts. Cataract is clearly a multifactorial disease, and different factors

are associated with different types of opacities. The findings are encouraging for those risk factors at which simple, preventive strategies might be targeted, such as decreasing sun exposure, increasing antioxidant vitamin use, or smoking cessation. For example, use of UV-absorbing glasses and a hat would reduce exposure to UV-B light. However, because the amount of risk attributable to UV exposure is unknown, it is not possible to estimate the effect of such protection on the likelihood of developing a cataract that will require surgery.

Further research is needed to develop and assess the impact of strategies designed to reduce or retard the development of cataract. The potential saving in human suffering and cost that could result from preventing or retarding cataract development and progression, including the possibility of precluding development of functionally significant cataract in a large proportion of elderly, is enormous. At this time, management guidelines on reducing the risk of cataract cannot be provided.

Cost of Care

The panel found no published data regarding the frequency with which various preoperative, intraoperative, and postoperative services are provided in connection with extraction of a cataract or regarding the cost of those services. The panel, therefore, asked the AHCPR-funded Cataract Patient Outcomes Research Team (PORT) to assess both the content and cost of an episode of cataract surgery through analyses of a sample of 1986-87 Medicare claims data (for beneficiaries 65 years of age or older). In addition, a sample of 1987-89 private insurance claims data (for individuals under age 65) was purchased from MEDSTAT Systems, Inc. (Ann Arbor, MI).[3]

In summary, this analysis suggests that Medicare expended approximately $3.4 billion in connection with cataract surgery in 1991. Of this, only $64 million (2 percent) is estimated to have been spent on miscellaneous ophthalmic diagnostic tests and perioperative medical services. The primary determinants of Medicare's cost of cataract surgery are thus the overall frequency with which cataract surgery and YAG laser capsulotomy are performed and the amounts paid for these core components of an episode of cataract surgery.

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[3]The data presented in this section are derived from Earl P. Steinberg, MD, MPP, et al., "The Content and Cost of an Episode of Cataract Surgery," manuscript submitted for publication.

Methodology

Development of Methods and Questions

To prepare for the development of the guidelines by the panel, a meeting of the Ad Hoc Literature Review Group was held in Washington on July 19, 1990. The purpose was to develop a list of literature search questions to be answered by the literature review. It was decided that the questions would be oriented toward aspects of the care of patients with functional impairment due to cataract as they relate to outcome. The questions were divided into 13 categories. At the same time, criteria for including and excluding articles in the literature review were also developed.

A two-pronged approach to the literature search was devised in which both content and methodologic quality would be evaluated. The Ad Hoc Literature Review Group unanimously agreed that content relevance was of prime importance in establishing the literature to be reviewed for this panel. To achieve this goal, teams of content experts would first review and select the publications based on content relevance. Methodologists would then review the selected publications and come to consensus regarding quality and conclusions, using criteria established to ensure appropriate rigor. A content review team leader and a methodologist for each category would be appointed.

This overall approach, the literature search questions, and the inclusion/exclusion criteria developed by the Ad Hoc Literature Review Group were approved by the guideline panel at its first meeting in August 1990. The content review team leaders were then selected by Denis O'Day, MD, Panel Chair, on the basis of known expertise in the area under consideration. Subsequently, team leaders in collaboration with Dr. O'Day appointed literature review team members. A similar approach was used to select methodologists for the project.

The members of the Ad Hoc Literature Review Group decided to use the data bases of the National Library of Medicine as the foundation. Because of the limitations of timeliness and breadth inherent in such data bases, less formal methods of literature search were also used. These included reviewing research and professional meeting abstracts, writing to journal editors of impending and relevant articles, reviewing government studies, and surveying interest groups for relevant information.

As a result of the informal literature search process, two articles considered worthy of review were brought to the attention of the Ad Hoc Literature Review Group during the open forum. These articles dealt with cataract practice patterns and were sponsored, cited, and widely distributed by special interest groups advocating certain types of practice patterns. These articles were not published in a peer-review journal and were not annotated by the National Library of Medicine.

In light of the unique circumstances surrounding these publications and for the benefit of the panel, it was decided to review these separately. These full reviews are included in Appendix A in the *Guideline Report.* They are the reviews by William Stason, MD, and Steven Woolf, MD, MPH, of the Society of Geriatric Ophthalmology Special Report on Cataract Care and the review by Dr. Woolf of the Battelle Study, "Outcomes of Cataract Surgery With Co-Managed Postoperative Care" (Revicki, Brown, and Adler, 1990).

Eligibility Criteria. The literature review for developing the guidelines was based primarily on published articles identified by searchers of electronic data bases. They adhered to the following eligibility criteria:

- Articles were included only if the report focused on more than 10 individuals.
- Articles describing triple procedures for corneal disease or glaucoma were excluded.
- Research reported in articles must have focused on senile and presenile cataracts and cataracts related to diabetes. Congenital cataracts were excluded from the review, and traumatic cataracts were also excluded.
- Animal studies were excluded.
- Post mortem studies were excluded unless other patient data were included.
- Unpublished literature was acceptable.

The literature review was limited to articles published in English from January 1, 1975, through December 31, 1990. (For the review of surgical techniques and complications, the search was extended through April 1991.) However, peer reviewers brought to the panel's attention some relevant literature published after the cutoff date. If it appeared that the more recent items might alter the guideline, they were included in the review. Additional information on these inclusions is given in the *Guideline Report.*

Reference Sources. Trained searchers developed and conducted searches of electronic data bases at the National Library of Medicine. The specific search strategies used are included in Appendix A in the *Guideline Report.* The combined data base sources used for searching were:

- MEDLINE (1975 to January 26, 1991).
- Cumulative Index to Nursing and Allied Health Abstracts file (CINAHL) (1983 to August 1, 1990).
- Psychological Abstracts (1975 to September 1, 1990).
- Catline (books) (1975 to August 1, 1990).
- Health (1975 to August 1, 1990).
- Dissertation Abstracts (1960 to September 1, 1990).
- Science Citation Index (1987 to March 1991) (SCISearch).

Other nonelectronic sources of references were also utilized. These included:

- Ad hoc notification by guideline panel or team members regarding specific reports that should be included.
- References obtained from a machine-readable reprint file from the RAND Corporation project on cataracts.
- An article by Kerry B. Kemp and Barbara Boardman in *Vision Research: A National Plan, 1983-1987.*
- Several articles from *Health Devices*, a technology assessment journal that conducts engineering assessments of medical devices on phacoemulsification.
- An article from the Battelle Human Affairs Research Center entitled "Outcomes of Cataract Surgery With Co-Managed Postoperative Care" (Revicki, Brown, and Adler, 1990).

In addition, peer reviewers submitted a few items not previously identified through the systematic literature review. If these items met the inclusion criteria and provided additional information, they were included. (See Appendix Q of the *Guideline Report* for more information on these inclusions.)

Definitions Used in Constructing Literature Search Questions. The following definitions were used in constructing literature search questions to be answered by the literature review:

Timing: Timing of surgery refers to the stage of disease, as specified by degree of functional impairment.

Volume: Number of surgical procedures performed by surgeon in specific time period.

Positive Outcome: Degree to which the presurgical functional impairment is relieved by the surgery, as defined by the following types of benefits perceived by the patient, members of the patient's family, or the ophthalmologist:

- Increased ability to read or do close work.
- Increased ability to perform minimal everyday activities.
- Increased opportunity to continue or resume function or occupation (working, playing, driving) due to improvement in vision.
- Restoration of functional ability to precataract level.
- Increased mobility.
- Increased independence.
- Better uncorrected vision.
- Improved color vision.
- Reduced glare disability.
- Improved depth perception.
- Increased ability to retain a quiet eye with no treatment-induced disorders.
- Increased patient satisfaction with the results of surgery.
- Improved sense of mental well-being.
- Improved self-esteem.
- Relief from fear of going blind.

- Increased ability to avoid injury.
- Increased interpersonal contact.
- Increased opportunity for medical observation of the internal eye for incipient or impending diseases.

Negative Outcome: The failure to relieve (improve) preoperative functional impairment as perceived by the patient, the patient's family, or the ophthalmologist. In addition, negative outcome refers to the development of complications that either impair the patient's visual function or consume resources. Examples of negative outcomes include:

- Death.
- Loss of eye.
- Loss of vision.
- Risk to the other eye.
- Presence of preventable and significant side effects and complications.
- Infection.
- Retinal detachment.
- Imbalance in the power of the lenses.
- Glare problems.
- Corneal problems.
- Hyphema.
- Increased intraocular pressure (IOP).
- Cystoid macular edema.
- Expulsive hemorrhage.
- Glaucoma.
- Ptosis.
- Dislocated IOL.
- Increased risk of pupil dilation.
- Systemic morbidity as a result of the operation.
- Dissatisfied patient.
- Quality of life worsened.
- Painful eye.
- Disorientation.
- Black patch psychosis.
- Self-harm through overestimating abilities.
- Fractured hip.
- Increased need for ocular medication.
- Adverse systemic effects of ocular drugs.
- Increased ultraviolet exposure.
- Decreased mobility.
- Need for further surgery.
- Loss of job.
- Failure to improve.

Specific Search Questions. The search questions constructed by the Ad Hoc Literature Review Group are discussed in the relevant chapters of this report. The categories of search questions are as follows:

Category 1: Natural History
Category 2: Referral Pathways and Access to Care
Category 3: Setting and Providers of Care
Category 4: Tests of Visual Function: Contrast Sensitivity Testing, Glare Testing, and Potential Vision Testing
Category 5: Specular Photographic Microscopy
Category 6: Indications for Cataract Surgery
Category 7: Preoperative Medical Evaluation
Category 8: Anesthesia
Category 9: Surgical Techniques and Complications
Category 10: Second Eye Surgery
Category 11: Postoperative Care
Category 12: Rehabilitation
Category 13: Posterior Capsular Opacification-YAG Capsulotomy
Category 14: Selection of IOL
Category 15: Nonsurgical Management of Cataract

Categories 14 and 15 were not researched.

Selection of Potentially Relevant Articles

Printouts of the citations were sent to expert literature reviewers (abstract reviewers) to review and from which to select articles that appeared to be potentially relevant. In this first stage, the purpose of the selection process was to be "sensitive" as opposed to "specific." That is, the goal was to avoid overlooking any potentially relevant articles rather than to identify only articles that were definitely relevant to the question at hand.

Complete copies of the selected articles were retrieved from periodicals and reviewed by team leaders to determine whether articles satisfied the eligibility criteria. The same articles were also reviewed by methodologic evaluators for each team. The methodologist and team leader then communicated with one another to agree on a common set of articles deemed relevant for evaluation.

Development of Literature Evaluation Forms

The process of developing literature evaluation forms was concurrent with the process of identifying relevant articles. Two forms (a methodologic form and a content form) were used in evaluating an article. The methodologic form was developed by the methodologist for the team, and it addressed the following issues:

- Type of study design employed.
- Description of the patient population.
- Inclusion/exclusion criteria.
- Bias in patient selection.
- Sample size.

- Use of a comparison group.
- Potential bias in selection of patients or controls.
- Standardization of exposure or intervention.
- Standardization of definition and measurement of outcome.
- Use of masking of randomization.
- Duration of followup specified.
- Handling of attrition.
- Consideration of nonindependence of eyes for a single patient.
- Issues related to external validity of the study.

The content form typically was designed to address the specific search questions decided on by the Ad Hoc Literature Review Group in July 1990 and approved by guideline panel members in August 1990. These forms were generally developed by team leaders, with assistance from other Ad Hoc Literature Review Group members as needed.

Assessment of Content and Methodology

Once the final set of articles was selected for abstraction by content and methodology reviewers, copies of selected articles were mailed to members of each team for review and evaluation.

All articles mailed to the content reviewers were masked, so that the authors, their institutions, and the journal and year of publication were not visible. Articles were assigned to methods and content teams, with a common set of articles assigned to at least two members of those teams to allow assessment of interrater reliability.

Completed forms for the content reviews were returned to the team leader for summarization and analysis, and completed methods forms were returned to the methodologist for the same.

Interrater reliability for both the content and methods review was assessed by comparing duplicate abstractions by separate readers for the same article. For sections where only a few articles were evaluated, all articles were read and abstracted in duplicate and compared for reliability. When large numbers of articles were assessed, a sample of all articles was read and abstracted in duplicate and compared. Specific methods are described in the relevant chapters.

For the most part, no formal statistical analyses were done; rather the evidence was summarized in tabular form. The major reason for this was that study designs tended to vary substantially in clinically and methodologically significant ways. For example, patient eligibility criteria, outcome measures and definitions, and duration of followup varied substantially, precluding meaningful "pooling" of results.

Writeup of Literature Reviews

The panel was provided with drafts of the literature review results as they were completed. In some instances, the panel requested additional

information that the members thought should be sought from the available literature. For example, in the case of potential vision, after the literature was initially reviewed and summarized in draft form, the panel requested a second review of the literature in order to identify articles containing data relevant to the effect of macular disease on the sensitivity and specificity of potential vision testing.

The reports for each of the sections of the *Guideline Report* were constructed in the same way. The Results section listed the questions initially identified by the Ad Hoc Literature Review Group and described the literature relevant to each question that met the inclusion criteria. The results of the literature review were also summarized in evidence tables.

In the chapters, text labeled "Discussion" centered on, first, the methodology of the studies included in the review and, second, their results. Sections labeled "Conclusions" were based primarily on the literature review. Only rarely did the panel present conclusions that were not based on the literature. When they did, they were careful to note where conclusions were based on the literature and where they expressed consensus opinion.

Consensus Process

In several cases, notably preoperative medical evaluation, there was very little available literature specifically appropriate to cataract surgery. In this case, guidelines that are not specific to cataract surgery were described, referencing the general medical literature where possible. Another example of a situation with little or no relevant literature was the chapter on Referral Pathways. When the panel needed to reach a consensus on an issue because of lack of data in the published literature, the mechanism was as follows: the person responsible for the chapter for which little or no data were available would write the chapter and conclusions based either on related literature, prior guidelines, or opinion. As with all chapters of the *Guideline Report*, the draft was distributed by mail to panel members for feedback. Using input from panel members, the responsible person would revise the draft several times prior to the next scheduled panel meeting. At the panel meeting, there would be considerable discussion regarding all conclusions, but in particular about conclusions for which a consensus had to be reached because there were no available data. At each panel meeting, drafts would be rereviewed and discussed again at length. The consensus process always involved panel members, and they were the only ones allowed to vote. No final decisions were made on chapters and their conclusions other than at panel meetings.

2 Guideline: Referral Pathways and Access to Care

The process of caring for a patient with functional impairment due to cataract should start when a disability is recognized. A diagnosis of cataract can be made by any of a number of health care providers, including ophthalmologists, optometrists, family physicians, and internists. However, in order to decide whether to have the cataract removed, a patient must understand the likely benefits and potential risks of undergoing cataract surgery. Such an understanding of the risks and benefits comes from a discussion with the ophthalmologist who might perform the surgery. This surgeon is responsible for ensuring that the patient understands the likely benefits and potential risks of cataract surgery in his or her case before making a decision about whether or not to proceed with surgery.

Background

More than 1 million cataract procedures are performed under the Medicare program each year, making it the leading therapeutic surgical procedure for Americans age 65 and over. Overall, it is estimated that about 1.35 million cataract extractions were performed in the United States during 1991. Thus, how patients with functional impairment due to cataract come to receive care and how this process of interaction with the health care system influences the outcome for the individual are matters of great importance.

Literature Review

Methods

The purpose of the literature review was to identify and review those articles that contained information on the referral pathways for patients with functional impairment due to cataract. The referral sources to consider included self, internist, family practitioner, other ophthalmologist, other physician, other optometrist, nurse, social agency, social worker, health fairs, and nursing home screenings. (For a full description of the literature review and its results, see Appendix B in the *Guideline Report.*)

Results

The results of the literature review are given here and summarized in Evidence Tables B-1 to B-3 in Appendix B of the *Guideline Report.*

Question 1: Is there evidence to support or refute an association between referral source and detection of cataract?

A case-control study (Harrison, Wild, and Hobley, 1988) indicated that ophthalmic opticians in a district of Great Britain tended to detect and refer patients with cataract at an earlier stage in the disease than general practitioners, resulting in a greater proportion of the general practitioners' patients requiring cataract surgery. An uncontrolled case series provides descriptive information, including visual acuity and presumptive diagnosis, for referrals from an optometry clinic to various medical services in a Veterans Administration Hospital (Newcomb and Potter, 1979).

Bezan (1987) suggested that not all optometrists are referring their patients with visually significant cataract to ophthalmologists for surgical consultation. A survey of 60 Oklahoma optometrists was performed to evaluate their management of cataract patients. The survey asked: "When you examine a patient who has a cataract that is significantly affecting vision, how often do you send the patient to an ophthalmologist for a surgical consultation?" Forty-five percent referred the patient all the time, 45 percent most of the time, and 10 percent occasionally.

The Oklahoma survey measured the perceived knowledge of the optometrists about various forms of correction for aphakia. The article concludes that "the means of aphakic correction most commonly used today—the intraocular lens (IOL)—is the one about which optometrists feel the least knowledgeable."

Also in this survey, a concern was expressed over "one-way" referrals, "i.e., the patients are not returned to the optometrist for postsurgical refractive care." "Only 26.7 percent of the optometrists reported having their patients returned after cataract surgery all of the time." The impact of one-way referral on the optometrists' willingness to refer was not measured. The broader applicability of the results of this survey is unclear.

Question 2: Is there evidence to support or refute an association between referral source and timing of surgery?

No article was found to address this question.

Question 3: Is there evidence to support or refute an association between referral source and outcome (surgical or nonsurgical)?

Two articles provided information on outcome of surgery in relation to referral source. A case-control study (Kennedy, Brubaker, O'Fallon et al., 1985) indicated that patients with cataract who came from locales outside of the county where a tertiary care center (Mayo Clinic) is located were more likely to have diabetes mellitus and require more concurrent ophthalmic surgery procedures than cataract patients from the county in which the Mayo Clinic is located. The cases of patients referred from outside the community, therefore, were more complicated than those of community referrals. There was no significant difference in the proportion achieving 20/40 or better visual acuity after cataract surgery between community and referral patterns. A study of 57 patients referred from an

optometry clinic for medical review of possible cataract (Newcomb and Potter, 1979) provides descriptive information only on the action taken by the ophthalmologist. All 57 cataract diagnoses were confirmed, and 19 (33 percent) underwent cataract surgery. However, patient outcomes are not described. The article is methodologically deficient.

Question 4: Is there evidence to support or refute an association between marketing techniques and detection of cataract?
Question 5: Is there evidence to support or refute an association between marketing techniques and timing of cataract surgery?
Question 6: Is there evidence to support or refute an association between marketing techniques and outcome (surgical or nonsurgical)?

Two articles provided evidence that was indirect in nature about associations between marketing techniques and detection of cataract, timing of surgery, and outcome (see Evidence Table B-2 in the *Guideline Report*). In a survey of members of the American Academy of Ophthalmology (Leaming, 1990), 20 percent of the respondents indicated that they felt advertising their services was a necessary practice, whereas a survey of ophthalmologist-members of the American Society of Cataract and Refractive Surgeons, a cataract surgeon society, indicated that 27 percent felt advertising was necessary to their practice (Leaming, 1988). Both surveys suffered from low response rates, thereby making their broader applicability unclear.

Question 7: Is there information on cost and/or cost-benefit issues?

There was no direct information on cost and/or cost-benefit issues in referral for management of cataract. One article (Roberts and Zalta, 1988) indicated that, in comparison to actual costs obtained from claims data, if physicians accepted Medicare reimbursement for cataract surgery, costs would be considerably reduced (see Evidence Table B-3 in the *Guideline Report*). However, the applicability of the study is limited to those settings where Medicare reimbursements constitute the sole reimbursement for cataract surgery.

Conclusions From the Literature Review

No definite conclusions can be reached as a result of this review. Two papers, however, suggest that referral rates could be influenced by the referral source. General practitioners in Great Britain tended not to refer patients until surgery was imminent. Optometrists surveyed in Oklahoma tended not to routinely refer patients with symptomatic cataracts.

Conclusions of the Panel

The issues surrounding referral for management of functional impairment due to cataract are complex. Although they are integral to fundamental aspects of the quality of care, they have received, so far, very

little attention in the medical or sociologic literature. From the patient's perspective, even if surgery is not immediately considered, the purpose of referral is to ensure that cataract is the cause of the decreased vision and that other causes are not present. A variety of ocular, neurologic, and systemic diseases may cause impairment in the presence of lens opacities. They may arise in patients with a known diagnosis of cataract. Some of these conditions are treatable if diagnosed in a timely manner.

The process of referring a patient with functional impairment due to cataract for care starts when a visual disability is recognized. A diagnosis of cataract can be made by any of a number of health care providers, including ophthalmologists, optometrists, family physicians, and internists. However, in order to decide whether to have the cataract removed, a patient must understand the likely benefits and potential risks of undergoing cataract surgery. Such an understanding of the risks and benefits comes from a discussion with the ophthalmologist who might perform the surgery. This surgeon is responsible for ensuring that the patient understands the likely benefits and potential risks in his or her case before the patient makes a decision about whether to proceed with surgery. Some conditions require cataract surgery for their treatment even though the cataract is not the vision-limiting factor. Other conditions will preclude any benefits from cataract surgery.

It is in the patient's best interest that recognition of a visual disability lead to consultation with an ophthalmologist who has the requisite skills to confirm the diagnosis and to provide the appropriate treatment. Patients appear to reach the surgeon through a variety of means, including self-referral; referral by family or friends; patients of eye care specialists; other physicians, including family practitioners, primary care physicians, internists, and other specialists; and other ophthalmologists, optometrists, opticians, ophthalmic registered nurses, registered nurses, or nurse practitioners. In many instances, patients develop cataracts while under the routine eye care of other ophthalmologists or optometrists. These patterns are well established throughout the country and appear to provide a satisfactory referral mechanism for many patients. However, as a result of the review of recent data (published after the December 31, 1990, cutoff date for the systematic review of the literature), the panel is concerned that these patterns of referral may not apply universally. For example, certain circumstances; economic factors; social issues, particularly those of a racial nature; language barriers; and the uneven distribution of medical resources may inhibit appropriate referral and access to care (Javitt, McBean, Nicholson et al., 1991; Sommer, Tielsch, Katz et al., 1991).

Recommendations for Research

The issues addressed in this literature review, particularly the impact of self-promotion by the ophthalmologist and optometrist, and the influence of different routes of referral on surgical rates and outcomes are also

important considering that large variations in cataract surgery rates within small geographic areas have been reported (Holahan, Berenson, and Kachavos, 1990). Therefore, the panel recommends that these aspects of the referral mechanism be subjected to further inquiry.

In addition, several other issues related to access to care and referral are pertinent because of the impact that they may have on overall quality of care, surgical rates, and the appropriate use of the surgical procedure. They were not addressed in the literature review and require targeted research. These are as follows:

- Optometric-ophthalmologic referral relationships with a formal or informal contractual basis.
- Mass screening in nursing homes and in other venues by ophthalmologists and optometrists to identify patients with cataract.
- Ophthalmologic or optometric ownership of surgery centers.
- Managed-care organizations and cost-containment policies of managed-care organizations.
- New reimbursement policies for Medicare patients.
- Proposed preferred provider organizations for patients with cataract.

3 Guideline: Setting and Providers of Care

Cataract surgery should be performed where patients can receive quality care in a safe environment, close to home if at all possible or close to the best social support system of family and friends. The ophthalmologist who performs the surgery has the responsibility and ethical obligation to the patient for care during the postoperative period.

Background

During the past 15 years, improvements in cataract surgical techniques have led to major changes in the surgical setting and the approach to care before and after surgery. In the past, cataract surgery was an inpatient procedure requiring hospitalization for up to 7 days. Today, most cataract surgery is performed as an outpatient procedure in an ambulatory surgery center or a hospital-based outpatient surgical center. The care rendered in these two settings may not be assessed as rigorously as the care rendered in the hospital setting. In the hospital setting, there is formal institutional surveillance of peer review and quality assurance, a joint hospital accreditation process, plus the informal surveillance of other physicians and the many different types of staff personnel that may be present.

Traditionally, the ophthalmologist who performed cataract surgery provided the preoperative and postoperative care. Changes in Medicare coverage and reimbursement have encouraged a number of ophthalmologists to work with independent, nonsurgically trained providers to provide perioperative care. Efforts by a few ophthalmologists to provide less direct care and still achieve successful results have in some instances resulted in situations where the ophthalmologist who performed the surgery relegated postoperative care to nonophthalmologist health care providers.

On April 1, 1987, Medicare coverage was expanded to permit reimbursement to optometrists as physicians (as defined in the Social Security Act governing Medicare), within the legal authorizations of the States in which they practice. The expansion of coverage did not delineate the division of responsibility between an ophthalmologist and an optometrist working independently or between an ophthalmologist and an optometrist working in the same setting providing shared care.

It is not known whether changes in the setting of surgery and in the delegation of perioperative care to those working independently of the ophthalmologist who performed, or is to perform, the surgery are medically safe and appropriate, and whether these changes have altered the outcome, cost, and quality of providing cataract surgical care. Is it safe and

appropriate for a surgeon to delegate all or part of the postoperative care to an independent provider who was not involved in the surgery and may not have the education, competence, or knowledge to make the requisite clinical judgments?

Nothing is known regarding the quality and long-term outcome of cataract surgery under these circumstances, particularly as they relate to the diagnosis and management of complications, nor is there information regarding differences in cost. Is there any difference in the cost of providing surgery in one setting over the other? Is there any difference in cost when the postoperative care is provided by an ophthalmologist as opposed to an optometrist? In a report issued in April 1989, the Office of the Inspector General expressed concern over situations in which abusive referral arrangements resulted in Medicare overpayments and kickbacks (Department of Health and Human Services, 1989).

Presently, there are no data in the published literature regarding the most appropriate division of responsibility for postoperative care following cataract surgery. However, there is a generally accepted belief that the operating ophthalmologist, being the most knowledgeable about what took place at surgery, is in the best position to diagnose and deal with surgically related complications and has the ultimate responsibility for a successful outcome.

Literature Review

Methods

The purpose of the literature review was to determine whether there is evidence in the published literature to support or refute an association between the outcome of cataract surgery and the overall setting of care. (See Appendix C in the *Guideline Report* for a full discussion of the literature review process.)

Results

Each of 18 articles was evaluated with reference to the search questions. The results of the literature review are given here and summarized in Evidence Table C-1 in Appendix C of the *Guideline Report.*

Question 1: Is there evidence to support or refute an association between outcome following cataract surgery and the identity and/or qualifications of the individual performing the initial workup (optometrist, ophthalmologist, generalist/primary care physician)?

No articles were found to address this question.

Revicki, Brown, and Adler (1990) identified a pattern of optometrists referring cataract patients to ophthalmologists at ambulatory eye centers for complete eye examinations and surgery if needed. The article did not

analyze the association between this referral pattern and outcome of surgery.

Question 2: Is there evidence to support or refute an association between outcome following cataract surgery and the length of association between the patient and the physician postoperatively?
Question 3: Is there evidence to support or refute an association between outcome following cataract surgery and the location of the surgery (ambulatory surgical center vs. hospital)?

No articles were found to address these questions.

Question 4: Is there evidence to support or refute an association between outcome following cataract surgery and the volume of cataract surgery performed by the provider?

Six studies (Farrell and Deichman, 1981; Kersten and Kolder, 1982; Neuhaus and Straatsma, 1983; Schanzer and Wilhelmus, 1985; Straatsma, Meyer, Bastek et al., 1983; Wong and Kline, 1982) of residents in training in the United States revealed that supervised resident surgeons in training had a high surgical success rate, and their complication rate during their first 100 or fewer cases did not differ significantly from that of more experienced surgeons. One study (Sutton, 1980) of surgeons in training in England reported a higher incidence of late complications in patients undergoing cataract surgery with intraocular implantation. The linkage of the higher complication rate to the surgeon's experience is uncertain, since this late complication of corneal decompensation may well have been due to poor intraocular lens (IOL) design (iris loop lenses).

Question 5: Is there evidence to support or refute an association between outcome following cataract surgery and the qualifications and/or identity of the individual providing postoperative care (medical doctor vs. optometrist, surgeon vs. delegated medical doctor, high-volume vs. low-volume provider)?

No articles were found to address this question.

Revicki, Brown, and Adler (1990) described complication rates when optometrists followed the patients during one or more visits in the 3 months after surgery. The study concluded that patients receiving postoperative care delivered by optometrists had visual outcome and complication rates that were comparable to those reported in the medical literature where all care is delivered by ophthalmologists.

The study was done in response to a Congressional Office of Technology Assessment report on "comanaged care" that implied that optometrists, because of differences in training compared with ophthalmologists, might not deliver acceptable postoperative care following cataract surgery (Kemp and Boardman, 1988).

Problems with the study relate to both internal validity—the extent to which the study provides valid information about the sample studied—and external validity—the extent to which the results are generalizable to other

settings. Internal validity problems relate to sample selection, data collection, unstandardized interventions, choice of outcome measures, data analysis, and the inferences of the authors. Problems with external validity include selection bias, study intervention, lack of proper comparison groups, and the inferences drawn by the authors. Thus, it is not possible, on the basis of this publication, to support or refute the hypothesis that postoperative care delivered by optometrists and ophthalmic surgeons is comparable with that administered by the ophthalmic surgeon alone. (For full review, see Appendix A in the *Guideline Report.*)

Question 6: Is there evidence to support or refute an association between outcome after cataract surgery and the distance of the patient's home from the surgical and/or office site?
Question 7: Is there evidence to support or refute an association between outcome after cataract surgery and the availability of emergency care?
Question 8: Is there evidence to support or refute an association between outcome after cataract surgery and the context and identity of the person(s) providing postoperative home care (self, family, visiting nurse, nursing home, other)?

No articles were found to address these questions.

Question 9: Is there information on an association between outcome after cataract surgery and cost and/or cost-benefit issues?

No article was found addressing the cost-benefit issue of outpatient surgery in an ambulatory surgery center vs. a hospital-based outpatient setting. Four articles described how outpatient surgery is less costly than inpatient surgery (Bloom and Krueger, 1988; Davies, Limacher, and Powell, 1987; Stephenson, 1985; Williamson, 1975). However, this issue is no longer current.

No article was found to suggest that the volume of cases referred by the surgeon was a factor in determining cost effectiveness.

No study was found to document that having optometrists perform part or all of the postoperative care was more cost efficient than having ophthalmologists perform the care.

No article was found to link availability of emergency care with cost.

Discussion

In the classification of these papers, only three broad categories were identified. One set focused on the clinical outcomes and complications associated with the provision of cataract surgical care by ophthalmologic resident physicians in training, often in comparison with faculty surgeons. There were seven studies in this category. The second category included five studies that focused on the measurement of the impact of the ambulatory provision of cataract surgical care in relation to inpatient surgery. The remainder dealt with various aspects of the organization and

provision of ophthalmologic care (such as cost, quality, patient satisfaction, and the provision of care by optometrists and nurses to cataract patients) on the outcomes and complications of cataract surgery.

There is great variability among the studies reviewed. There appears to be a lack of consensus as to the most salient clinical or policy questions. Within those small clusters of projects that seem to study the same general issue, there is great variability in how the problem is formulated and in the way the principal variables are measured and results interpreted.

The lack of a "gold standard" for the measurement of the most important clinical outcomes seems to hamper these studies as a whole.

Few of the studies accounted for baseline differences among subjects (case mix) that might influence the clinical outcomes of greatest interest.

Summary

The set of papers reviewed here are, in general, methodologically weak and rely on nonexperimental methods with unspecified and unstandardized measures of either the independent or dependent variables of greatest importance. Most of the design inadequacies of these studies are correctable within feasible bounds of cost and convenience for those who would seek to answer these questions through further research. Moreover, the answers to these questions will make available information of considerable value to emerging public policy in the field of health and medical care.

Conclusions From the Literature Review

It is not possible to draw firm conclusions from the available scientific literature on these subjects regarding the influence of the type of provider, type of setting, or other features of the setting within which cataract surgical care is provided and the most common clinical outcomes (e.g., visual acuity and surgical complications). There seem to be strong suggestions in the existing literature that surgery performed (under supervision) for cataracts can be satisfactorily provided by residents with 2 or 3 years of postgraduate training with little difference in the critical indicators of clinical outcomes.

Conclusions of the Panel

Site of Surgery

In the absence of data in the published literature, the panel reached the following conclusions by consensus.

Surgery should be performed where the patient can receive quality care in a safe environment, close to home if at all possible or close to the best social support system of family and friends. An outpatient setting can be in a hospital or in an independent surgery center. The selection of the site is

the responsibility of the ophthalmologist who performs the surgery because the ophthalmologist is ultimately responsible for the care of the patient and is best qualified to judge the adequacy and safety of an operative setting.

The selection of the site of surgery should not be influenced by any financial relations between the operating ophthalmologist and the surgical facility or with the owners of the operating room. The selection of the site of surgery should not be influenced by the source of the patient referral.

The proximity of the setting for preoperative and postoperative care to the surgical site is important. In most cases, it is preferable that the perioperative care and surgery be performed in the same community. Proximity to the surgeon facilitates good postoperative care and is especially important when complications arise.

Sometimes a patient may choose to have surgery at a site far from home so that the postoperative course is with family or friends who can provide social, psychological, and practical support through the early postoperative period.

When the patient with cataract seeks surgery by an ophthalmologist located far from home, the provision of postoperative care by the ophthalmologist who performs the surgery becomes impractical; in that instance, the ophthalmologist should educate the patient about the importance of the continuum of the care process involved in cataract surgery. This includes the preoperative phase, the surgical procedure, and the period of postoperative care. If the patient still desires to have the surgery far from home, the ophthalmologist who is to perform the surgery should make formal and explicit arrangements before surgery for the provision of appropriate postoperative care that includes the capacity for dealing with complications and emergencies in a timely manner. The arrangements should include advice regarding temporary accommodations in the area where surgery is to be performed.

If anyone other than the operating ophthalmologist is to provide all or most of the postoperative care, then the operating ophthalmologist has an obligation to inform the patient before surgery of the arrangements and of the relative qualifications of the postoperative caregiver. The ophthalmologist assuming responsibility for the patient's postoperative care should be fully conversant with the surgical procedure and any unusual events or complications that occurred at the time of surgery and be fully capable of providing appropriate surgical intervention if required.

Providers of Care

The literature review failed to reveal useful information on important issues regarding providers of care. The panel reached the following conclusions by consensus.

From the patient's perspective, the operating ophthalmologist has a unique insight into and understanding of the patient's postoperative conditions, since he or she performed the surgery. Individual differences in

cataract and individual differences in patient responses to surgery may lead to variations in the immediate postoperative outcome even in an uncomplicated operation.

The panel unanimously agreed that since the ophthalmologist who performs the surgery does so after discussing his or her assessment of the risks and benefits with the patient and after obtaining informed consent, and since that ophthalmologist has the most intimate knowledge of what took place at the time of surgery, he or she has the responsibility and ethical obligation to the patient for care during the postoperative period. The responsibility and obligation arise on the basis of the covenant that exists between the surgeon and the patient (see Ethics: The Relationship Between Caregiver and Patient, in the Overview).

From the patient's perspective, the period of postoperative care spans the interval from the conclusion of surgery until the goal of surgery is achieved by the attainment of stable improved vision. In the absence of complications, this usually occurs by 3 months after the surgery and coincides with the prescription of a final refractive correction. It also marks the point at which wound healing has sufficiently advanced so that the integrity of the eyeball has been reestablished and most short-term intraoperative and postoperative complications have been diagnosed and treated.

If ophthalmic medical and surgical postoperative complications develop, it is the obligation of the ophthalmologist who performed the surgery to provide treatment or, with the consent of the patient, to refer him or her to another ophthalmologist, depending on the nature of the problem. This treatment may need to extend beyond the postoperative period.

The surgeon must examine the patient the day after surgery, initiate appropriate postoperative treatment, monitor the patient's recovery from the surgery, diagnose and treat postoperative complications, or refer the patient to an ophthalmologist better able to deal with those complications (e.g., corneal decompensation, endophthalmitis, retinal detachment, and unexplained visual loss) and perform surgical revision when appropriate (e.g., cut sutures for treatment of postoperative astigmatism). To fulfill these responsibilities, the surgeon must examine the patient periodically until he or she is confident that the patient has fully recovered from surgery, a process that usually takes 6-12 weeks.

The surgeon cannot abrogate his or her responsibility for the patient's postoperative care; however, certain components of that care can be delegated to one or more members of a team of appropriately trained professionals.

At the present time, most ophthalmologists in the United States provide all of the postoperative care in their offices. Other ways of providing postoperative care utilize optometrists, visiting registered nurses, social workers, and other health care professionals. Some optometrists provide postoperative cataract care with varying amounts of involvement.

Some optometrists assume the care of the patient from the ophthalmologists soon after surgery and refer detected medical and surgical complications back to the ophthalmologist for management. Some optometrists manage postoperative complaints independently, and others become involved in the care only after the eye has healed and is ready for refraction. In certain areas of the country, the patient receives part of the postoperative care at home from ophthalmic registered nurses.

These different patterns of postoperative care and the respective roles of the operating ophthalmologist, optometrist, visiting nurse, and other health care professionals are varied, vaguely defined, and lack standardization. The panel agreed that even with these new "team" approaches, the ophthalmologist who performed the surgery remains responsible for the surgical outcomes. Therefore, in addition to the responsibilities outlined above, the ophthalmologist must do the following:

- Be aware of the patient's needs, particularly as they relate to the eye, visual function, surgery-related complications, and the coexistence of systemic diseases.
- Be aware of the type and degree of competencies required to meet the patient's needs.
- Delegate or refer care to other providers if it is deemed appropriate and in the patient's best interest.
- Educate and advise the patient about the roles and competencies of specific individuals participating in the postoperative care.
- Be aware of and acknowledge cost considerations.

There should be a shared sense of responsibility among all those participating in a patient's postoperative care and visual rehabilitation. Part of this responsibility is to maintain sufficient communication so that care is coordinated and quality of care is monitored and maintained.

The literature search did not identify any study that addressed the effect of the services provided by ancillary medical personnel (e.g., ophthalmic technicians or technologists) on the outcome of cataract surgery. This is largely because most of these providers work within the operating ophthalmologist's office under his or her direct supervision and their contributions to patient care have not been analyzed separately or as part of a team approach.

The lack of studies on the availability of emergency care is probably because there is generally no problem of availability when ophthalmologists follow their own patients. Professional ophthalmic standards require the ophthalmologist who performs the surgery to be responsible for providing emergency care or to make arrangements for another ophthalmologist to do so.

The current practice of ophthalmology residents in training providing care, including cataract surgery under appropriate supervision, is satisfactory.

Recommendations for Research

The panel recommends that research be undertaken to determine if the outcome of surgery is influenced by the setting for cataract surgery and the type of provider of postoperative care and if the outcome is influenced by the volume of surgery performed by the surgeon.

The panel recommends that, in the best interest of the patient, research be funded to evaluate patterns of practice, including the team approach, and their impact on the quality of care provided. It also recommends that, to assure quality of care, requirements be established for all providers of postoperative care to attain clinical competence. The panel places a high priority on this recommendation, but it must be interpreted in light of the fundamental obligation of the surgeon to be responsible to the patient for postoperative care.

Patient preferences regarding the role and responsibility of the ophthalmologist who performed the surgery in the preoperative and postoperative phase should be studied.

4 Guideline: Preoperative Ophthalmic Testing in Patients with Cataract

The decision to perform cataract surgery is generally made after judging the effect of the cataract on the patient's visual function and/or the cataract's contribution to functional impairment, after assessing the patient's visual needs, and after a thorough consideration of the potential risks associated with surgery.

Background

The decision to perform cataract surgery is generally made after a judgment of the effect of the cataract on the patient's visual function and assessment of the patient's visual needs. Visual complaints are compared with visual acuity measurements and the results of the eye examination to confirm the presence of a cataract and rule out or otherwise gauge the potential impact of other causes of visual loss. Snellen visual acuity is the most universally accepted method of assessing visual function, but in a number of patients, it may not accurately or adequately reflect the level of impairment caused by cataracts.

Newer techniques for evaluating visual dysfunction caused by cataract include contrast sensitivity and glare testing. Like Snellen acuity, contrast sensitivity testing is an index, or measure, of visual function. However, contrast sensitivity testing attempts to determine the ability to perceive objects of varying contrast. Glare testing is used clinically in an effort to assess the functional impairment of a patient who is disabled by glare. Certain types of cataracts, such as posterior subcapsular (PSC) cataract, may cause disabling glare in daylight conditions or from oncoming headlights during night driving despite relatively good Snellen visual acuity measured in a darkened room.

In addition, potential vision tests and specular photographic microscopy have been developed to determine the likelihood of a successful outcome after cataract surgery. Potential vision tests attempt to predict the visual acuity that might be expected as a result of cataract surgery. Specular photographic microscopy provides information on endothelial cell counts and morphology, which are thought to be useful in identifying patients in whom the cornea is unlikely to withstand surgery, i.e., patients likely to develop corneal edema.

Assessment of Preoperative Tests

The approach taken in assessing the value of all of these tests for the purpose of development of this guideline is that typically applied to diagnostic tests in any area of medicine. A number of criteria must be satisfied for the test to be considered appropriate for use.

First, the test must be valid, that is, both acceptably sensitive and specific. Sensitivity is defined as the proportion of patients a test correctly identifies as having the disorder or condition of interest. Specificity is the proportion of patients a test correctly calls "negative."

The assessment of a test's sensitivity and specificity depends on a comparison of the test's results and "the truth" with regard to whether a disorder or condition (e.g., disabling glare) is actually present. Unfortunately, a true "gold standard" is often unavailable or not used properly in research studies of this type. The gold standard must be judged for its appropriateness and quality based on prior evidence and clinical experience. If the gold standard is inappropriate or inadequate, the estimated sensitivity and specificity of the test being evaluated will be inaccurate.

Second, the test must be repeatable (reliable or precise). Variation in the observer (interobserver or intraobserver) and variation related to the test itself (lighting in room, size of the pupil) can affect the test's reliability.

The yield of a test is defined as the amount of previously unrecognized disease diagnosed and brought to treatment as a result of performing the test. Yield is dependent on both sensitivity and the prevalence of the disorder of interest. Prevalence is defined as the proportion of the population with the disorder within a specified time period. The higher the prevalence, the higher is the yield from the test.

The concept of the predictive value of a test unites the concepts of sensitivity, specificity, and prevalence. A positive predictive value is defined as the proportion of patients testing positive who actually have the condition or disorder of interest. If the prevalence of a disorder is low, even a very specific test will produce a large number of false positives because most people being tested, including many of those found to be positive, have no disease.

Before being accepted as clinically useful tools, diagnostic procedures should be evaluated in well-designed studies. Results from examinations on patients diagnosed through the use of the "new" test should be compared with results on the same patients diagnosed by an already established technique. When this type of comparison is being made, the order in which the new and old test are given should be randomly assigned to avoid learning curve effects on the data collected. In addition, data from the new test or from the gold standard test should be masked as to the values obtained for the comparison test performed on the same patient.

Literature Review Methods

In developing these guidelines, the methods used by the literature review teams for evaluating contrast sensitivity, glare testing, and potential acuity were nearly identical. The panel developed topic-specific questions. The National Library of Medicine designed and ran literature searches. The printouts generated by the three searches were grouped together and reviewed as a whole by the same literature review team. Part of the reason for this approach was that many articles address more than one topic.

Additional articles of potential relevance, not identified by the National Library of Medicine search, were gleaned from reference lists of relevant articles and by notification from other investigators and clinicians.

Many more articles on these tests were published than are included here. The articles not included did not meet the general selection criteria outlined in Appendix A in the *Guideline Report* or the specific criteria described for evaluation of each test (Appendices D-G in the *Guideline Report*).

The literature review proceeded as described in Appendices A and D-F in the *Guideline Report*. Once the final selection of articles for all three topics was made (65 articles in all), reviews were conducted separately for each topic. Some reports were included in reviews for more than one topic. The methods used for evaluating specular microscopy were different and are described in full in Appendices A and G in the *Guideline Report*.

This section of the guideline addresses the use of preoperative testing in clinical practice for managing the adult patient with functional impairment potentially due to cataract. The tests and their intended uses are described, and the methods and findings of a formal literature review and consensus reached by the panel are detailed, together with recommendations for future research.

The guideline makes the distinction between visual impairment and functional impairment. Visual impairment refers to patient status measured in terms of the results of visual testing (i.e., Snellen visual acuity). Functional impairment refers to patient status in terms of the ability of the patient to perform everyday activities (see Organization of the *Clinical Practice Guideline* in Chapter 1), as reported by the patient or health care provider.

The purpose of this literature review was to identify and review those articles that contained information on contrast sensitivity, glare, and potential vision testing as tests of visual function for patients with functional impairment due to cataract. (For a full description of the literature reviews and their results, see Appendices D-F in the *Guideline Report*.) The questions for specular photographic microscopy are different and are detailed later in the chapter.

Contrast Sensitivity Testing

Test Description

Contrast sensitivity is a measure of the degree of contrast required to detect a test object. Snellen visual acuity measures the eye's ability to perceive high-contrast letters but does not adequately assess its ability to see low-contrast patterns. Contrast sensitivity testing attempts to determine the eye's ability to detect subtle variations of shading by presenting letters, figures, or sine wave gratings that are varied in contrast, luminance, and spatial frequency. Contrast sensitivity is determined by the lowest detectable contrast in which a subject is able to identify targets.

Numerous devices and methods have been developed to test contrast sensitivity. The simplest and least expensive methods employ reading cards or eye charts similar to those used in Snellen testing. More elaborate (and more expensive) methods involve the use of electronic devices (such as oscilloscopes) to generate sine wave gratings.

Literature Review Results

The results of the literature review are given here and summarized in Attachment 2 at the end of this document.

One hundred and nineteen papers on contrast sensitivity testing were reviewed by the contrast sensitivity content literature review teams. Ninety-eight of these were excluded because they did not meet the inclusion/exclusion criteria set forth by the guideline panel. A total of 21 papers were reviewed for content and methodologic quality. Of these, only 10 provided data relating to the questions specified by the panel.

For the 21 articles reviewed for content, there was, in general, excellent agreement among content reviewers for items on the content evaluation form. In a few cases where there was disagreement, one of the reviewers changed his or her mind on reevaluating the study in question, or a third content reviewer was asked to review the article and cast the deciding vote. There was very poor agreement among content reviewers about the type of study (e.g., clinical trials), and these questions were therefore referred to the methodology reviewers with no attempt made to achieve consensus among content reviewers.

The results of the methodologic review of the 10 articles relevant to the questions posed by the panel are summarized in Attachment 2.

Very few of the 10 relevant articles met any of the methodologic criteria pertinent to studies that assess a preoperative test. Only two studies set out to assess contrast sensitivity testing as a test to document patients' complaints of visual impairment that may be useful in a preoperative evaluation (Elliott, Hurst, and Weatherill, 1990; Koch, 1989). Eight studies described contrast sensitivity testing in patients with different ocular pathologies or different types and severity of cataracts (Elliott, Gilchrist,

and Whitaker, 1989; Hess and Woo, 1978; Howes, Caelli, and Mitchell, 1982; Lempert, Hopcroft, and Lempert, 1987; Maudgal, Stout, and vanBalen, 1988; Morris, Klett, Gieser et al., 1991; Singh, Cooper, Alder et al., 1981; Skalka, 1981a). These studies either did not use a gold standard for comparison of contrast sensitivity results or used one that was inappropriate for answering the questions posed in this literature review.

Question 1: Is there a correlation between the results of the test and the patient's level of functional impairment?

One study provided information regarding a correlation between contrast sensitivity test results and functional impairment due to cataract. This article (Elliott, Hurst, and Weatherill, 1990) described a case series of 33 patients with cataract in at least one eye and correlated contrast sensitivity with patient-reported functional disability. Contrast sensitivity was measured for both eyes (binocular) using a Pelli Robson letter chart (both sides). Functional disability was measured using a patient questionnaire of 20 questions. The questions were grouped into mutually exclusive categories pertaining to mobility, near vision, and discrimination. The correlations between binocular contrast sensitivity and mobility, near vision, and discrimination were –0.65, –0.60, and –0.49, respectively. (The negative correlation coefficient implies that functional disability decreases as contrast sensitivity score increases.) For the worse eye, the correlations between contrast sensitivity and mobility and near vision were –0.50 and –0.35, respectively; data were not provided for discrimination because the correlation was "not significant." For the better eye, the correlations between contrast sensitivity and mobility, near vision, and discrimination were –0.50, –0.67, and –0.43, respectively. Thus, the correlation between contrast sensitivity and functional disability was highest when binocular contrast sensitivity was used. The magnitude of several correlations was higher for contrast sensitivity than for visual acuity.

One study (Koch, 1989) provided information regarding the correlation between contrast sensitivity test results and patients' complaints of glare. The proportion of patients with false positive and false negative results for contrast sensitivity was neither better nor worse than for Snellen acuity testing, when those results were compared with the patient's complaint of glare as the gold standard. In addition, the correlation between contrast sensitivity test results and glare complaints was no higher than correlations between Snellen acuity and glare complaints.

Three studies measured correlations between contrast sensitivity and Snellen visual acuity (Elliott, Gilchrist, and Whitaker, 1989; Howes, Caelli, and Mitchell, 1982; Lempert, Hopcroft, and Lempert, 1987). These studies showed a correlation between contrast sensitivity and Snellen visual acuity, but there was no standardization of methods of contrast sensitivity or Snellen acuity measurement across studies. One study found a moderate to high correlation (r=0.44 to 1.0) between contrast sensitivity and Snellen acuity (Elliott, Gilchrist, and Whitaker, 1989) for cortical, nuclear, and

PSC cataracts. Contrast sensitivity decreased as the severity of cataract increased. This latter result was also obtained by a second study (Howes, Caelli, and Mitchell, 1982). In a third study, as contrast sensitivity decreased, mean Snellen acuity decreased in eyes with PSC cataract. For normal eyes, the trend was the same, but the decrease in Snellen values was less pronounced (Lempert, Hopcroft, and Lempert, 1987).

A fourth study (Hess and Woo, 1978) involving only 10 subjects used a ratio of cataract to normal eye acuity as a comparison. This ratio is not clinically meaningful, and its correlation with the contrast sensitivity measure was poor (r=0.1). Furthermore, its use would be limited to patients with uniocular cataract. Although all of these studies are based on the premise that functional visual impairment involves more than poor acuity, none of them assesses patients' overall function or ability to perform everyday activities.

One study (Maudgal, Stout, and vanBalen, 1988) provided information on the sensitivity and specificity of contrast sensitivity testing for detection of cataracts. The gold standard for comparison was the clinical examination. This information is not applicable, therefore, to the setting where it is already known that the patient has a cataract and where the purpose of the test is to provide information preoperatively regarding the potential value of cataract surgery.

In two studies of contrast sensitivity (Arden gratings), no visual acuity data were provided (Singh, Cooper, Alder et al., 1981; Skalka, 1981a). One study reported that Arden scores correlated better than Snellen visual acuity with subjective patient complaints (Skalka, 1981a). In another study, eyes with cataract had a mean score that was significantly different (worse score) from normal eyes (14.5±3 vs. 12.25±1.44, respectively, for "plate 6" [Singh, Cooper, Alder et al., 1981]). After pupil dilation, there was an improvement in Arden scores for eyes with cataract but not for normal eyes.

Question 2: Is there information on the type or degree of functional impairment detected by the test that is not detected by history and routine physical examination alone?
Question 3: Is there evidence to support the value of the test in detecting patients who are not suitable for surgery?
Question 4: Is there evidence to identify a relationship between the use of the test and the timing of surgery?
Question 5: Is there evidence to identify a relationship between the use of the test and the volume of surgery performed annually by the ophthalmologist ordering the test?
Question 6: Is there information on costs and/or cost-benefit issues?

No articles were found addressing these questions.

Question 7: What is the relationship between preoperative test results and postoperative test results in patients in whom no intraoperative or postoperative complication occurred?

No article contained information on the relationship between preoperative and postoperative contrast sensitivity results in at least 10 patients in whom no complications occurred.

One article (Morris, Klett, Gieser et al., 1991) contained information on this relationship for a group of patients with and without complications. In this study, postoperative contrast sensitivity was accurately predicted in 10 of 15 patients. Four of the five inaccurate predictions were in patients with visual acuity worse than 20/200. Data were available for only 15 of 20 (75 percent) patients originally enrolled in the study.

Conclusions of the Panel

Based on the findings from the literature review, the panel reached the following conclusions.

- In patients with cataract, the relationship between contrast sensitivity test results and functional impairment has not been adequately examined, although one study (Elliott, Hurst, and Weatherill, 1990) has demonstrated a correlation between binocular and better eye contrast sensitivity and patient-reported functional impairment due to vision. There is also published evidence in the low-vision literature, as summarized by the American Academy of Ophthalmology (1990), that suggests that contrast sensitivity test results are correlated with the degree of functional impairment in patients without cataract. These data and their relevance to the patient with cataract will be reviewed in a subsequent update of the guideline.
- Contrast sensitivity testing does not differentiate between visual loss due to cataract and visual loss from other causes.
- There is no commonly used contrast sensitivity test for which preoperative and postoperative results have been compared except the interferometer. In this case, only one published article exists (Morris, Klett, Gieser et al., 1991). It indicated that postoperative contrast sensitivity was accurately predicted in 10 of 15 cases. Inaccurate predictions occurred in patients with visual acuity worse than 20/200.
- In the absence of other studies comparing preoperative with postoperative contrast sensitivity results and in the absence of preoperative vs. postoperative assessments of functional impairment, the panel is unable to assess the clinical usefulness of information from contrast sensitivity testing, above and beyond that obtained from routine history and ocular examination, in determining whether a patient would benefit from cataract surgery.

Recommendations for Research

Further research should be undertaken to determine the clinical utility of contrast sensitivity testing as a source of valid information with respect

to functional impairment due to cataract above and beyond that obtained through history and routine ocular examination.

Glare Testing

Test Description

Glare is an impairment in visual function caused by the presence of a source of light located in the visual field. Patients with a cataract often complain of glare because cataracts and other opacities in the ocular media cause light entering the eye to be scattered, thereby producing glare. Glare testing attempts to reproduce the symptom of glare and to quantify the degree of visual impairment it causes. A typical patient with disabling glare complains of poor vision in well-lighted situations but may have nearly normal acuity when measured in a darkened room. Visual acuity may fall precipitously when retested in ambient light. Glare disability is generally determined by comparing a subject's visual acuity with and without the presence of a bright-light source directed at the patient's eye.

A variety of methods and devices for testing glare are described in the published literature. Some of the devices used for this purpose are simple and inexpensive, such as a penlight or room lights. More elaborate instruments costing hundreds of dollars, such as the brightness acuity tester (BAT), or thousands of dollars, such as the Miller-Nadler glare tester, are also available.

In the United States, glare disability testing is widely used to evaluate patients with cataract, in part because in many States, peer review organizations request the results of this test at the time of precertification for cataract surgery, particularly in patients with good visual acuity.

Literature Review Results

The results of the literature review are given here and summarized in Attachment 3.

Question 1: Is there a correlation between the results of the test and the patient's level of functional impairment?

One study examined whether there was a correlation between the results of glare testing and the patient's level of functional disability. This article (Elliott, Hurst, and Weatherill, 1990) described a case series of 33 patients with cataract in at least one eye and correlated glare scores with patient-reported functional disability. Glare disability was measured using a Mentor BAT, which measured reduction in visual acuity due to glare (GD_{VA}) and reduction in letter contrast sensitivity due to glare (GD_{CS}). The BAT can take only monocular measurements, so all testing was done on the eye with the worse visual acuity. Functional disability was measured with a patient questionnaire of 20 questions. The questions were grouped into mutually exclusive categories pertaining to mobility, near vision, or

discrimination. The correlation between the worse eye's GD_{VA} and mobility was "not significant," although no correlation coefficient was provided. The correlations between the worse eye's GD_{VA} and near vision and discrimination were 0.61 and 0.51, respectively. Only the correlation between the worse eye's GD_{CS} and discrimination was provided (r=0.45) because the corresponding values for mobility and near vision were "not significant." The correlation between patient-reported functional disability related to near vision and discrimination was higher for worse eye glare disability than for visual acuity.

One study (Koch, 1989) examined the correlation between the results of glare testing and patients' glare complaints. The correlations between the results of the Baylor visual function tester and glare complaints were 0.36 and 0.61 at low and high levels of glare, respectively. The correlation between the Stereo Optical Glare Tester and glare complaints was 0.68. The article did not specify the impact of glare on the patients' everyday activities and did not indicate how the glare complaints were measured.

Six studies examined the association between the results of glare testing and outdoor visual acuity (Hirsch, Nadler, and Miller, 1984a; Holladay, Prager, Trujillo et al., 1987; Neumann, McCarty, Locke et al., 1988; Neumann, McCarty, Steedle et al., 1988a and 1988b; Prager, Urso, Holladay et al., 1989). The BAT was used in three of these studies (Holladay, Prager, Trujillo et al., 1987; Neumann, McCarty, Locke et al., 1988; Prager, Urso, Holladay et al., 1989). In one study (Holladay, Prager, Trujillo et al., 1987), normals showed no decrease in visual acuity caused by either the BAT or outdoor testing. For patients with cataract, the correlation between outdoor visual acuity and BAT was r=0.84. The BAT predicted outdoor acuity to within one line in 73 percent of the subjects in a second study (Neumann, McCarty, Locke et al., 1988) and overpredicted glare disability in 81 percent of subjects at the high setting and 42 percent at the medium setting in a third study (Prager, Urso, Holladay et al., 1989).

In one article, the correlation between the results of glare testing (using author's device) and outdoor acuity was better for those facing the sun than for those not facing the sun (Hirsch, Nadler, and Miller, 1984a), both for subjects with and without cataracts. In another, Snellen visual acuity was decreased by two lines in 70 percent of subjects when they faced the sun (Neumann, McCarty, Steedle et al., 1988a). A third study found that the Miller-Nadler glare tester predicted outdoor acuity within one line for 47 percent of all eyes in the study.

Two other studies relate to this question. One study (Maltzman, Horan, and Rengel, 1988) compared visual acuity with and without penlight glare in 114 cataract patients. All patients with nonglare visual acuities of 20/40 or worse also saw 20/40 or worse with penlight glare. Forty-five percent of patients with nonglare visual acuities of 20/40 or better (sic) had an acuity of 20/40 or worse with penlight glare. Another study (Hard, Abrahamsson, and Sjostrand, 1990) found decreased visual acuity and contrast sensitivity

in the presence of glare. The decreased contrast sensitivity was independent of visual acuity.

Several studies examined the correlation between the results of glare testing and visual acuity by the type of glare test used. One study found that the correlation varied depending on the glare test used (Neumann, McCarty, Locke et al., 1988). Outdoor visual acuity was predicted to within one line in 73 percent of the eyes for BAT, 69 percent for True Vision Analyzer (TVA), 56 percent for VisTech, 47 percent for Miller-Nadler, and 15 percent for Eye Con tests, in which all tested eyes were diagnosed with cataract. The same results were reported in a second article (Neumann, McCarty, Steedle et al., 1988b), perhaps on the same patients, for the Miller-Nadler test alone. (It predicted outdoor visual acuity to within one line in 47 percent of the eyes.) The authors also provided information regarding the cataract type and the ability to predict outdoor acuity (see below); however, a third study (Prager, Urso, Holladay et al., 1989) found that in eyes with cataract, accuracy to within one line occurred in 36 percent of eyes for Miller-Nadler, 17 percent for high luminance BAT, and 45 percent for medium luminance BAT. The Miller-Nadler test tended to underestimate glare disability (as measured by outdoor visual acuity) in 62 percent of eyes, and the BAT overpredicted in 81 percent of eyes at high settings and 42 percent at medium settings. This study also found significant interobserver variability in glare test results.

In terms of the correlation between glare test and visual acuity for specific types of cataract, one study showed high correlations for cortical ($r=1.0$) and nuclear ($r=0.77$) cataract but not for PSC ($r=0.12$) (Elliott, Gilchrist, and Whitaker, 1989). A second study demonstrated that the Miller-Nadler test predicted outdoor acuity to within one line in 50 percent of eyes with nuclear cataract, 40 percent with nuclear plus PSC, and 52 percent with other cataracts (Neumann, McCarty, Steedle et al., 1988b). A third study found a weak correlation between glare score and visual acuity in subjects with PSC cataracts or normal eyes (Abrahamsson and Sjostrand, 1986). Thus, glare scores have the lowest correlation with visual acuity in patients with PSC cataract. Therefore, the test may be of greatest value in these patients.

Question 2: Is there information on the type or degree of functional impairment detected by the test that is not detected by history and routine physical examination alone?
Question 3: Is there evidence to support the value of the test in detecting cases that are not suitable for surgery?
Question 4: Is there evidence to identify a relationship between the use of the test and the timing of surgery?
Question 5: Is there evidence to identify a relationship between the use of the test and the volume of surgery performed annually by the ophthalmologist ordering the test?
Question 6: Is there information on costs and/or cost-benefit issues?

No articles were found providing useful information on these questions.

Question 7: What is the relationship between preoperative test results and postoperative test results in patients in whom no intraoperative or postoperative complication occurred?

Three studies addressed the relationship between preoperative and postoperative glare test results (Levin, 1989; Masket, 1989; Weiss, 1990), and all three showed an improvement between preoperative and postoperative scores related to cataract surgery. In one study, mean decimal acuity in conditions of glare improved from 0.06 preoperatively to 0.22 postoperatively (Weiss, 1990). Mean Miller-Nadler glare scores improved from 55.2 percent preoperatively to 7.6 percent postoperatively in a second study (Masket, 1989) and from 15 percent preoperatively to 10 percent postoperatively, using TVA, in a third study (Levin, 1989).

No studies examined a correlation between glare scores and functional impairment. Although these studies demonstrated that subjects' scores on the glare test improved after surgery, the studies do not provide evidence that the patients' complaints of glare or their functional impairment also improved. Thus, no study demonstrated that patients' complaints of impairment due to glare were accurately detected by the glare tester and that both the complaints and glare scores improved after surgery.

Two studies examined the test-retest reliability of glare testing. One showed an excellent correlation between first and subsequent glare tests when the test was performed on patients with cataract ($r=0.95$) but a less good correlation when patients were aphakic ($r=0.54$) or had normal vision ($r=0.06$) (Hirsch, Nadler, and Miller, 1984b). A second study (van Lith and Hekkert-Wiebenga, 1983) examined test-retest reliability for letter contrast sensitivity with and without glare in patients with cataract and found the reliability to be very good ($r=0.83$ without glare; $r=0.92$ with glare).

One major deficit noted throughout the published literature on glare testing is the lack of established standard equipment, conditions of administration, and scoring of the test. For example, there is no consensus regarding the most appropriate type of glare source, background illumination, target configuration, or criterion for abnormality justifying surgery.

Conclusions of the Panel

Based on the findings from the literature review, the panel reached the following conclusions.

- A number of devices are available for testing glare. It is difficult to compare them, however, because standards have not been established for glare source, background illumination, target configuration, and other factors.

- There is some evidence in the published literature that glare test results are reproducible in patients with cataract. More data are needed to evaluate the reproducibility of glare test results in patients with different types of cataract and different types of symptoms potentially attributable to glare.
- Glare disability symptoms are not specific to cataract. As with most tests of vision, glare disability testing is not able to differentiate between visual loss due to cataract and visual loss due to other causes.
- Several studies have adequately shown that abnormal glare test results improve after cataract surgery. Whether symptoms potentially attributable to glare and glare-related functional disability decrease postoperatively in such patients, however, has not been reported in the published literature.
- The correlation between glare test results and functional impairment in patients with cataract was examined in one study (Elliott, Hurst, and Weatherill, 1990). In that study, there was a correlation between glare disability, as measured by a reduction in visual acuity in the worse eye, and functional disability related to near vision and discrimination. The magnitude of these correlations was greater than the magnitude of the correlations between visual acuity and these functional disabilities. One cannot determine from the data that are reported, however, whether the differences in the magnitude of these correlations are either statistically or clinically significant.
- The correlation between glare test results and visual acuity is high in patients with cortical and nuclear cataracts and low in patients with PSC cataracts. This suggests that, if glare testing provides useful information regarding functional disability due to glare, it is most likely to be of value in patients with PSC cataracts.
- There are three ways that glare testing might be used in the context of a patient with functional impairment potentially due to cataract.

  Application 1: As a stand-alone objective measure of functional impairment due to cataract.

  The panel agrees that there is no evidence in the published literature that the test can be used as a stand-alone objective measure of functional impairment due to cataract justifying cataract surgery.

  Application 2: As a source of valid information concerning functional impairment vs. visual impairment due to cataract, over and above information provided by the history and physical examination.

  The panel agrees that there is no evidence from the published literature to support the use of the test as a source of valid information concerning functional impairment due to cataract, over and above that provided by the history and ocular examination.

  Application 3: As a source of valid information on visual impairment that will assist the ophthalmologist in advising the patient regarding the

suitability or deferral of surgery when used in conjunction with the history, ocular examination, and measurement of visual acuity.

The panel believes that glare testing may be useful in the clinical evaluation of patients who complain of glare, or who have symptoms potentially attributable to glare, and who have a cataract (particularly a PSC cataract), yet measure good Snellen acuity in the testing circumstances of an office. However, the published literature has not yet provided data that demonstrate that postoperative improvements in glare test results are associated with improvement in glare symptoms or with symptoms potentially attributable to glare.

Given the current state of knowledge, it is reasonable to perform a glare test as part of the evaluation of patients who complain of glare, or who have symptoms potentially attributable to glare, and who have a cataract (particularly a PSC cataract) and good Snellen acuity. However, glare testing should not be required by utilization review or quality assessment organizations, such as peer review organizations, as objective documentation of visual disability sufficient to justify the potential benefit of surgery.

The panel believes that the glare test is not useful in patients with cataract who do not complain of symptoms potentially attributable to glare, regardless of their visual acuity.

Recommendations for Research

Glare testing may be of value in corroborating glare symptoms in some patients. The panel recommends that more research be performed on glare testing to clarify its role in the evaluation of the patient with functional impairment potentially due to cataract.

Potential Vision Testing

Test Description

Tests of potential vision have been developed in an effort to determine whether individuals with obviously impaired vision have a potential to see well after cataract surgery (i.e., the significant cause of their visual impairment is cataract rather than other pathology). Two basic types of tests, subjective and objective, are available. Subjective tests require the individual being tested to respond to questions asked about visual stimuli that are presented, and objective tests do not.

Subjective tests include the suprathreshold pinhole device, Maddox rod test, laser interferometer, Guyton-Minkowski potential acuity meter, and a number of devices that use blue field entoptic images. Some of these are simple and inexpensive, such as entoptic imagery and the Maddox rod test, whereas others are more expensive because of the cost of the instruments needed to perform them, such as the laser interferometer and potential

acuity meter (PAM). Objective tests are electrophysiologic tests in which the response to visual stimuli is measured electronically. Those evaluated in the literature include electroretinography and visually evoked potential.

Objective tests are generally more expensive than subjective ones because of the cost of electrophysiologic equipment and the expertise necessary to administer and interpret them. Such tests are generally not available in the private clinician's office. Instead, patients are usually referred to teaching institutions to obtain them.

Literature Review Results

The results of the literature review are given here and summarized in Attachment 4.

Question 1: Is there a correlation between the results of the test and the patient's level of functional impairment?

One study (Graney, Applegate, Miller et al., 1990) provided information regarding the association between the results of potential vision testing and the patient's level of functional impairment. This study provided measures of the impact of visual impairment on the ability of patients to perform their everyday activities. It measured everyday activities and mental status (Short Portable Mental Status Questionnaire) in 36 patients with cataracts and retinal disease. The impact of cataract surgery on 10 of the 14 activities could not be assessed because 85-100 percent of the subjects were already independent in these activities. In the remaining four activities, significant improvement occurred in traveling independently beyond walking distance and in independent shopping. Statistically significant changes did not occur in mental status after cataract surgery.

Of the remaining articles in this review, 29 provided some information on the relationship between the results of potential vision testing and postoperative visual acuity. These will be discussed under Questions 3 and 7.

Question 2: Is there information on the type or degree of functional impairment detected by the test that is not detected by history and routine physical examination alone?

Three articles (Graney, Applegate, Miller et al., 1988 and 1990; Miller, Graney, Elam et al., 1988) provided information potentially pertinent to the type and degree of functional impairment detected by potential vision testing. Two of the studies (Graney, Applegate, Miller et al., 1988 and 1990) reported predictive models based on clinical and functional data. The third study (Miller, Graney, Elam et al., 1988) compared results from laser interferometry, PAM testing, and an ophthalmologist's clinical judgment using the results of these two tests. The ophthalmologist predicted postoperative acuity exactly in 15 percent of cases, the interferometer did so in 15 percent, and the PAM in 11 percent. Predictions to within two

lines of actual postoperative acuity were 57 percent, 27 percent, and 26 percent, respectively. The study did not examine results from an ophthalmologist's clinical judgment alone.

Question 3: Is there evidence to support the value of the test in detecting cases that are not suitable for surgery?

The literature identified seven studies that suggest that subjective tests of potential vision, particularly the PAM and the laser interferometer, can provide an accurate indication of potential acuity in eyes with "relatively clear media" and a Snellen acuity better than 20/200 and no other eye disease (Christenbury and McPherson, 1985; Faulkner, 1983; Graney, Applegate, Miller et al., 1988; Ing, 1986; Minkowski, Palese, and Guyton, 1983; Spurny, Zaldivar, Belcher et al., 1986; Tabbut and Lindstrom, 1986). "Relatively clear media" was not well defined in the articles reviewed. The panel took the position that, for the purposes of drawing conclusions and recommendations, clear media would be defined as media through which the person performing the ocular examination could visualize the posterior pole. The studies applying this definition confirm that, in such eyes, history and clinical evaluation alone are as good as tests of potential vision in predicting visual outcome of cataract surgery.

In eyes with relatively clear media and clinical evidence of macular disease, it was not possible to determine from the available published literature whether any of the tests of potential vision were of value, although a number of studies concluded specifically that they were not (Bernth-Petersen and Naeser, 1982; Faulkner, 1983; Goldstein, Jamara, Hecht et al., 1988; Tabbut and Lindstrom, 1986). Most of these comparisons involved only small numbers of patients and did not have enough power to detect true differences. These studies failed to clearly define macular disease, however. Attachment 5 summarizes the results of testing in the presence of macular disease. (See Appendix F in the *Guideline Report* for a detailed discussion of the literature reviewed.)

In eyes with grossly opaque media, subjective tests of potential acuity are not accurate. In such eyes, objective tests (electroretinography or flash-evoked cortical potentials) can determine whether light signals are being received by the retina or brain, but these modalities do not measure fine visual function and their role is therefore limited.

Testing with Retinometers, Visometers, and Interferometers (see Attachment 5): The specificity of the potential vision test (i.e., the ability of the test to identify correctly patients who did have a poor surgical outcome) was presented, or could be calculated, in 11 of the 15 articles that assessed retinometers, visometers, and interferometers (Bernth-Petersen and Naeser, 1982; Cohen, 1976; Datiles, Edwards, Kaiser-Kupfer et al., 1987; Dubey, Masani, and Shroff, 1983; Enoch, Bedell, and Kaufman, 1979; Goldstein, Jamara, Hecht et al., 1988; Graney, Applegate, Miller et al., 1988; Grignolo, Moscone, Sobrero et al., 1988; Halliday and Ross, 1983; Spurny, Zaldivar, Belcher et al., 1986; Tabbut and Lindstrom, 1986).

The specificities from these studies ranged from 0.20 to 1.0, with little consistency across studies. Thus 20-100 percent of the patients with bad outcomes were correctly identified by these tests. The wide variability in these results was most likely due to variation in the study designs, the specific instrument used, procedures used for the preoperative testing and the postoperative evaluation of visual acuity, severity and type of cataract, and presence of comorbid ocular pathology.

The sensitivity of the tests (the ability of the test to correctly identify patients having "good" surgical outcomes) reported in these 11 articles also had a wide range. From 22 to 90 percent of the time, good outcomes were correctly identified before surgery by these tests. Nine of these studies reported a sensitivity of 0.70-0.90.

The remaining 4 of these 15 articles also reported a wide variety of results. In one study (Faulkner, 1983), the interferometer predicted visual acuity to within one line 88 percent of the time in patients with immature cataracts and no other ocular pathology, but it predicted visual acuity to be better than was actually achieved postoperatively (by greater than or equal to two lines) 96 percent of the time in patients with eyes having other pathology. The interferometer predicted postoperative acuity to within one line in 27 percent of cases (Miller, Graney, Elam et al., 1988) and to within two lines in 88 percent of cases with normal maculas and 66 percent of cases with abnormal maculas (Bryant, 1985). A fourth study (Angra and Pal, 1990) of patients undergoing cataract surgery indicated that the laser interferometer was "accurate" 35 percent of the time, falsely predicted a "poor outcome" 50 percent of the time, and falsely predicted a "good outcome" 15 percent of the time.

Potential Acuity Meters (see Attachment 5): The specificity of potential vision testing was presented, or could be calculated, in three of the nine articles assessing the PAM (Graney, Applegate, Miller et al., 1988; Minkowski, Palese, and Guyton, 1983; Spurny, Zaldivar, Belcher et al., 1986); specificity ranged from 0.71 to 0.92. Thus, the PAM correctly identified preoperatively 71-92 percent of cases that had poor acuity postoperatively. The PAM correctly identified preoperatively 33-94 percent of patients who had good postoperative visual acuity (Datiles, Edwards, Kaiser-Kupfer et al., 1987; Graney, Applegate, Miller et al., 1988; Minkowski, Palese, and Guyton, 1983; Spurny, Zaldivar, Belcher et al., 1986).

In addition, one study (Miller, Graney, Elam et al., 1988) reported that the PAM predicted visual acuity to within one line in 26 percent of cases; a second study (Severin and Severin, 1988a) reported that the PAM predicted visual acuity precisely in 26 percent of cases and to within two lines in 78 percent; and a third (Carpel and Henderson, 1986) reported predictions to within three lines in 86 percent of cases. One article (Ing, 1986) reported an accuracy of prediction to within two lines in 31 of 33 eyes (96 percent) tested.

Testing with Blue Field Entoptoscopy (BFE) (see Attachment 5): The specificity of potential vision testing was presented, or could be calculated, for three of the five articles assessing BFE (Grignolo, Moscone, Sobrero et al., 1988; Miris and Missotten, 1982; Sinclair, Loebl, and Riva, 1979). The BFE identified preoperatively 47-100 percent (specificity range 0.47-1.0) of those patients who ultimately had poor outcomes. Although the study by Lischwe and Ide (1988) provided information regarding both sensitivity and specificity of the BFE, the study included 8 patients with capsular opacities, excluded 15 patients with preoperative visual acuities worse than 20/200, and miscalculated the false positive and negative rates. Given these factors, the study's results could not be interpreted with any confidence. Murphy (1983) also provided some information, but sufficient reliable data were not provided to allow calculation of specificity.

The sensitivity of the BFE ranged from 0.5 to 0.95 for the three studies with data that could be evaluated. Thus, the BFE correctly identified 50-95 percent of patients who eventually had good surgical outcomes.

Clinical Indices and Judgment: Two studies examined clinical indices as predictors of good and bad surgical outcomes. One study of 36 patients with retinal disease (Graney, Applegate, Miller et al., 1990) found that the combination of three clinical variables (age, preoperative visual acuity, and retinal disease only in the periphery) tended to be a good predictor of surgical outcome (sensitivity = 0.83 and specificity = 0.85). Of the 13 patients who had successful surgeries (postoperative acuity 20/40 or better), 83 percent were predicted to have success by the index. Of the 23 patients who had unsuccessful surgeries, 85 percent were predicted not to have success by the index.

A second study (Graney, Applegate, Miller et al., 1988) reported the development of a predictive model on one sample of patients (a training set) and its validation on a second sample (a testing set). The clinical index, which included the patients' age, Snellen acuity, number of prescription medications, and frequency of reading the newspaper, had a sensitivity of 0.91 and specificity of 0.26. Thus, it was a good predictor of good but not poor surgical outcomes. On the other hand, both the interferometer and PAM used in the study were poor predictors of good outcomes (Se = 0.43 and 0.50, respectively) but good predictors of poor outcomes (Sp = 0.90 and 0.81, respectively).

A third study (Miller, Graney, Elam et al., 1988) compared the results of laser interferometry, the PAM, and an ophthalmologist's clinical judgment using data from both tests. Prediction of postoperative visual acuity to within one line occurred in 27 percent of cases with the interferometer alone, 26 percent with the PAM alone, and 57 percent for the ophthalmologist using all the data. This study was not designed to examine the ophthalmologist's clinical judgment alone. No data were provided on the distribution of the preoperative visual acuities of the patients.

Visually Evoked Potentials, Visually Evoked Responses, and Electroretinogram: Six of the 39 articles evaluated electro-ophthalmologic testing (Cruz and Adachi-Usami, 1989; Fukuhara, Oozato, Nojima et al., 1983; Skalka, 1981b; van Lith and Hekkert-Wiebenga, 1983; Vrijland and van Lith, 1983; Weinstein, 1977). One study did not provide postoperative data (van Lith and Hekkert-Wiebenga, 1983). A second (Skalka, 1981b) presented only negative predictive values, which are greatly dependent on the prevalence of the outcome of interest. Of 12 patients with preoperative acuities of 20/400 or better and a negative test result, 5 (42 percent) actually had postoperative acuities worse than 20/40. The negative predictive value dropped to 28 percent for the 25 patients who had preoperative acuities of count fingers or worse. The other four studies reported sensitivities that ranged between 0.1 and 1.0 and specificities that ranged between 0.5 and 1.0 (see Attachment 5).

Other Potential Vision Tests: Nine studies used a variety of tests to assess potential vision. Studies included: Baraldi, Enoch, and Raphael (1986) (gap test); Dubey, Masani, and Shroff (1983) (Maddox rod and two-point discrimination); Elliott and Hurst (1989), which was rejected because it did not meet all of the inclusion criteria (opacity lensometer 701); Enoch, Williams, Essock et al. (1985a) (vernier acuity, gap acuity, perimetry); Enoch, Williams, Essock et al. (1985b) (gap and perimetry test); Essock, Williams, Enoch et al. (1984) (2 dot vernier acuity); Miris and Missotten (1982) (color perception); Sinclair, Loebl, and Riva (1979) (two-light discrimination, color perception, Purkinje vascular entoptic phenomenon); and Whitaker and Deady (1989) (displacement threshold acuity). Most reported on 10-15 patients or on a subgroup of a larger sample.

One study (Elliott and Hurst, 1989), which was rejected because it did not meet all of the inclusion criteria, did not use postoperative outcomes and found no correlation (r=0.09) between the opacity lensometer and Logmar acuity for 45 cataract patients. The Maddox rod in one study (Dubey, Masani, and Shroff, 1983) of 100 cataract eyes had a sensitivity of 1.0 and specificity of 0.95 (see Attachment 5). Although the potential vision tests in this group were intriguing, there were not enough data from well-conducted studies or clinical trials to come to firm conclusions concerning their use in clinical practice.

Question 4: Is there evidence to identify a relationship between the use of the test and the timing of surgery?
Question 5: Is there evidence to identify a relationship between the use of the test and the volume of surgery performed annually by the ophthalmologist ordering the test?
Question 6: Is there information on costs and/or cost-benefit issues?

No articles were found addressing these questions.

Question 7: What is the relationship between preoperative test results and postoperative test results in patients in whom no intraoperative or postoperative complication occurred?

Eight articles (Adams and Shock, 1986; Bryant, 1985; Dubey, Masani, and Shroff, 1983; Faulkner, 1983; Goldstein, Jamara, Hecht et al., 1988; Lischwe and Ide, 1988; Murphy, 1983; Sinclair, Loebl, and Rivera, 1979) summarized under question 3 provide information on the relationship between preoperative potential vision measures and the postoperative visual acuity obtained in patients in whom no intraoperative or postoperative complication occurred, although no articles looked at this issue directly.

Conclusions of the Panel

Based on the findings from the literature review and panel discussion, the panel reached the following conclusions.

- Tests of potential vision can predict postoperative outcome reasonably accurately in eyes with a preoperative vision of better than 20/200 and media that are clear enough to confirm by examination that the posterior pole is normal. Evidence is lacking in the published literature that potential vision measurement increases the accuracy of the predicted outcome beyond that based on history and ocular examination alone.
- In eyes with opaque media and vision of 20/200 or worse, none of the tests of potential vision provides an accurate estimate of visual outcome after uncomplicated cataract surgery, although electrophysiologic tests may be useful in determining whether light signals are being received by the retina or brain (i.e., whether there is gross retinal disorganization).
- For eyes in which the posterior pole can be visualized, no conclusions can be drawn from the literature review about the influence of specific types of macular disease on the accuracy and value of tests of potential vision beyond what can be determined by ophthalmoscopic examination.
- There were no studies identified that address the issue of the predictive value of a collection or battery of potential vision tests in relation to postoperative visual acuity.
- There are three possible ways in which tests of potential vision could be used in evaluating a patient with functional impairment potentially due to cataract.

  Application 1: As a stand-alone objective measure of expected visual outcome after surgery for cataract.

  The panel concluded that tests of potential vision do not function as a stand-alone measure of predicted visual outcome after surgery for cataract, since they appear to be accurate only when:

  - Visual acuity is 20/200 or better.
  - The media are clear.
  - The posterior pole is normal on clinical examination.

Application 2: As a source of valid information concerning the visual outcome vs. function after cataract surgery, over and above that provided by the history and ocular examination.

The panel concluded that tests of potential vision do not provide information over and above that provided by the history and ocular examination to justify their use as a basis for decisionmaking about the visual outcome after cataract surgery.

Application 3: As a source of valid information on visual outcome after cataract surgery that will assist the ophthalmologist in advising the patient about the potential value of cataract surgery when used in conjunction with the history and ocular examination.

The panel concluded that the available evidence in the published literature suggests that tests of potential vision do not assist the ophthalmologist in predicting the outcome of surgery when used in conjunction with history and ocular examination.

Tests of potential vision add nothing to the history and ocular examination of a patient with cataract when the posterior pole can be visualized and is normal. Tests of potential vision are not accurate in predicting visual outcome after surgery in a patient with cataract when the posterior pole cannot be visualized. It is impossible to determine from the literature whether any of the tests of potential vision is of value when the posterior pole can be visualized and macular disease is present.

Based on this literature review and clinical judgment, the panel concluded that a test of potential vision should not be included as a preoperative test in the routine management of patients with functional impairment due to cataract. The panel recognizes that there may be a subset of patients (patients with specific types of macular degeneration and clear media) in whom such a test might be of value, but this has yet to be shown.

Many ophthalmologists find potential acuity measurements reassuring in situations in which they are uncertain whether other diseases, particularly mild to moderate atrophic macular degeneration, might limit postoperative vision rehabilitation. However, there are no data that have substantiated the value of potential vision testing in this circumstance, even though such testing might be helpful.

Recommendations for Research

The panel recommends that properly designed studies be performed to assess the value of preoperative tests for potential vision in eyes with cataract and macular disease. These should include further investigation of the methods of potential vision testing that are already in existence. Reports of the results of evaluations of potential vision tests in patients with cataract should be more specific with regard to definition of media clarity, the presence of and type of macular disease, and the time at which

patients are classified as to the presence of macular disease (i.e., preoperatively or postoperatively).

The panel also recommends that future studies address the usefulness of individual tests as well as a battery or collection of potential vision tests and that additional methods be developed to predict visual outcome after cataract surgery.

Specular Photographic Microscopy

Test Description

Specular photographic microscopy is a research tool used to measure and record endothelial cell counts and to evaluate endothelial cell morphology. When endothelial cells are destroyed by disease or surgery, the remaining cells normally do not divide. Instead, they enlarge and spread out to cover the posterior corneal surface, thus decreasing the cell density (cell count) in a given area. Corneas with extremely low endothelial cell densities may decompensate, swell, and become cloudy with time. Although a precise lower limit cannot be defined, there is a variable lower limit of cell density in different patients below which the corneal endothelial cell layer cannot function adequately to maintain corneal clarity.

A cataract extraction procedure will usually result in some decrease in the endothelial cell density. Therefore, corneas with very low cell densities before cataract extraction are thought to be at greater risk for postoperative corneal decompensation and permanent corneal edema than are corneas with "normal" cell densities. Thus, there is a conceptual rationale for advocating the use of specular microscopy preoperatively to ascertain the cell density of the corneal endothelium and thereby assess a patient's risk of postoperative corneal decompensation.

The specular microscope provides a magnified view of a small area of corneal endothelial cells that is obtained by specular (mirrorlike) reflection. The specular image can be seen on routine slit lamp examination, but when a slit lamp is used, the magnification is less than when a specular microscope is used. Consequently, it may be difficult to discern individual cells with a slit lamp.

A specular microscope may be either a "contact" type (an applanating lens touches the cornea) or "noncontact" type (the microscope does not contact the eye but merely magnifies the image normally seen through the slit lamp). The contact specular microscope provides more magnification and is easier to focus, but it requires the use of a topical anesthetic on the eye. Both types of microscopes can be used by a trained technician.

Images of the endothelium seen with specular microscopy can be recorded on video tape or photographic film. The endothelial cell density and configuration can then be estimated from the video or photographic

image. The cell density can also be estimated during examination with the slit lamp, but this technique is more difficult to perform and less accurate.

Quantitative analyses of the morphology of endothelial cells also can be performed by digitizing the image obtained with the specular microscope. A variety of morphologic measures can be defined, such as the mean area per cell or the variation in cell area.

Literature Review

Methods. The purpose of the literature review was to identify and review those articles that contained information on specular photographic microscopy of the corneal endothelium in relation to functional impairment due to cataract. (For a full description of the literature review, see Appendix G in the *Guideline Report.*)

Results. The results of the literature review are given here and summarized in Attachment 6.

Question 1: Is there evidence to support or refute an association between the results of preoperative specular photographic examination of the endothelium and the outcome of cataract surgery?

None of the eight studies (Azen, Hurt, Steel et al., 1983; Bates and Cheng, 1988; Bates, Cheng, and Hiorns, 1986; Bourne and Kaufman, 1976; Irvine, Kratz, and O'Donnell, 1978; Kraff, Sanders, and Lieberman, 1980; Rao, Aquavella, Goldberg et al., 1984; Stur, 1988) reported data enabling the reader to calculate the sensitivity or specificity of preoperative specular microscopy results in predicting the occurrence of postoperative corneal decompensation. The proportion of patients with postoperative corneal decompensation in the eight studies varied from 0 to 34 percent.

- Two studies found that preoperative cell count was not associated with postoperative corneal decompensation (Bates, Cheng, and Hiorns, 1986; Rao, Aquavella, Goldberg et al., 1984).
- One study reported that no patients in the study had postoperative corneal decompensation and that all had "normal" preoperative cell counts (Irvine, Kratz, and O'Donnell, 1978).
- One study reported that no patients had postoperative corneal decompensation, although three patients had "abnormal" preoperative cell counts. These three patients had corneal problems, including penetrating keratoplasty for Fuchs' dystrophy and keratoconus, and history of blunt trauma (Bourne and Kaufman, 1976).
- One study of 161 patients found that 2 of 3 patients with postoperative corneal decompensation had "abnormal" preoperative cell counts (Stur, 1988).
- One study had five patients with postoperative corneal decompensation. Of these, preoperative specular data were available on three, and all three had "abnormal" specular microscopy; one had uncountable cells and two had low cell counts (Kraff, Sanders, and Lieberman, 1980).

- One study had a single patient with corneal decompensation but provided no preoperative data for that patient (Azen, Hurt, Steel et al., 1982).
- One study suggested that the preoperative cell area may vary more in patients who develop postoperative corneal decompensation (Rao, Aquavella, Goldberg et al., 1984), and another that the mean area of the smallest cell is greater in patients who develop postoperative corneal decompensation (Bates and Cheng, 1988).

The results of the methodology review indicated, overall, relatively poor quality scores for the eight studies, regardless of which evaluation criteria were applied (see Appendix G in the *Guideline Report*). This is, in part, because the primary objectives of the studies reviewed were different from the objective of the questions posed by the panel for development of the *Guideline Report.*

Question 2: Is there evidence to support or refute an association between the results of preoperative specular microscopy and indications or contraindications for surgery?

No article contained data suggesting that the results of specular microscopy are useful in defining indications or contraindications for surgery.

Question 3: Is there information on cost and/or cost-benefit issues?

No article contained information on cost and/or cost-benefit issues.

Conclusions of the Panel

The results of the literature review failed to establish an association between the results of preoperative specular photography of the corneal endothelium and the outcome of surgery for cataract. The panel concluded that there is currently no evidence in the published literature or compelling rationale to support routine use of specular microscopy in patients for whom cataract surgery is being considered. Most patients at risk of corneal decompensation from surgery can be identified through history and clinical examination. There is no empirical evidence from the published literature that suggests that use of specular photographic microscopy in routine preoperative assessment adds information of value, beyond that gained through careful history and clinical examination, in deciding whether to proceed with cataract surgery or which procedure to perform.

The panel further concurred that, although the published literature does not provide evidence supporting use of specular photographic microscopy in the routine workup, there may be specific instances in which the endothelial cell count can contribute information pertinent to clinical decisionmaking. For example, there are patients with moderate degrees of endothelial disease and/or a history of previous intraocular surgery or intraocular inflammation for whom the test might be warranted. It is in these patients that a test to determine the status of the endothelium would

be most helpful. However, the irregularity of the posterior surface layer in such patients may render the endothelium difficult to visualize. Further research on this subgroup of patients is warranted.

Other Preoperative Tests

The following tests are not indicated as part of the preoperative workup for cataract surgery unless special circumstances, as documented in the patient's chart, justify them.

- Formal visual fields.
- Fluorescein angiography.
- External photography.
- Corneal pachymetry.
- B-scan ultrasonography.
- Specialized color vision tests.
- Tonography.
- Electrophysiologic tests.

5 Guideline: Treatment

Functional rehabilitation as a result of visual improvement is possible in the vast majority of patients and should be the goal at each stage of treatment.

Nonsurgical Management

For the patient developing cataracts, nonsurgical methods of management include patient education and reassurance about the cause of visual disability and the prognosis. In the developmental stage of nuclear sclerosis, a common type of cataract, myopia is induced, and changing the spectacle lens prescription will often improve vision. The use of strong bifocals, magnification, appropriate lighting, and other visual aids often satisfies the new vision requirements as the cataract progresses. Dilation of the pupil may allow the patient to view around the central posterior subcapsular (PSC) cataract. During this period of early cataract development, such measures may be successful for many patients in meeting their visual needs without recourse to surgery. However, the glare experience from such a cataract may be unacceptable, particularly when the intensity of ambient light is high or when the individual is facing high-intensity light, as in night driving.

Surgical Management

No test adequately describes the effect of cataract on the patient's visual status or functional ability. The decision to perform cataract surgery cannot and should not be made on the measurement of Snellen visual acuity alone; the likely degree of visual improvement and its impact on the quality of life must be weighed against the risk and cost of surgery. Although not a definitive measure of visual dysfunction, simple Snellen acuity is the most universally used index of visual function. Other, newer techniques for evaluating visual function are under investigation, but their reliability and standardization have yet to be established (see Chapter 4 and Adamsons, Rubin, Vitale et al., 1992; Cink and Sutphin, 1992, articles published after the cutoff date for the systematic literature review). Until reliability and standardization are established, clinical judgment combined with Snellen acuity remains the best general guide to the appropriateness of surgery. However, it is recognized that an individual's particular functional and visual needs, environment, and risks may vary widely and must be taken into account.

Indications for Surgery

The purpose of cataract surgery is to reduce and ideally to eliminate or remove functional impairment caused by the presence of a cataract. Only in unusual circumstances is cataract surgery performed for other reasons. How the patient and the ophthalmologist come to the decision to proceed with cataract surgery is the subject of this part of the guideline.

Literature Review

Methods. The purpose of the review was to identify the appropriate indications and contraindications for cataract surgery. (For a full description of the literature review, see Appendix H in the *Guideline Report.*)

Results. The questions identified by the panel are as follows.

1. **Is there evidence to support or refute an association between outcome, with and without surgery, and specific indications for surgery?**
2. **Is there evidence regarding the outcome of surgery in patients whose other eye is legally blind?**
3. **Is there information on cost and/or cost-benefit issues?**

The 48 papers selected were reviewed. None of these papers addressed the questions specified by the panel.

Conclusions

In most circumstances, cataract surgery is considered a nonemergency procedure. It is indicated when the cataract reduces visual function to a level that interferes with everyday activities of the patient. The severity of the interference can range from simple symptoms of glare disability to reduced ability to perform recreational activities and difficulty with reading, driving, employment, and performing other everyday activities.

The appropriateness of cataract surgery at each level of disability depends on the complete assessment of the overall visual function and the needs of the patient as well as adequate informed consent. Surgery for cataract is considered when medical, optical, and environmental measures have proved inadequate for the patient's visual requirements. The patient should make the decision to proceed with surgery on the basis of the ophthalmologist's recommendation and after considering subjective, objective, and educational criteria. However, the indication for surgery is founded on the patient's requirement for better vision and the patient's reasons for undergoing surgery. In almost all circumstances, surgery should not be performed solely because the cataract is present.

The ultimate decision regarding the desirability and timing of cataract surgery is determined by the patient and the ophthalmologist who is to perform the surgery. After a complete evaluation, the ophthalmologist

confirms the subjective and objective findings of vision reduction related to a cataract.

Unfortunately, as discussed in Chapter 4, there are no objective, stand-alone measures of functional impairment due to cataract that might serve as precise indications for cataract surgery. The development of such measures is a matter of high priority.

Recommendations for Care

The search of the literature did not reveal any information helpful in elucidating precise indications for surgery. Thus, pending the results from future research, the panel recommends the adoption of the following guidelines based on the *Preferred Practice Pattern*, "Cataract in the Otherwise Healthy Adult Eye," produced by the American Academy of Ophthalmology (1989). Although it is principally directed toward the elective decision to undergo surgery, it also considers those circumstances in which cataract surgery is indicated because the health of the eye or the health of the person is endangered. The panel recognizes that scientific evidence is lacking from the published literature to support the validity of these guidelines. Nevertheless, the *Preferred Practice Pattern*, which was developed by an exhaustive consensus method, has been available for 3 years and has not been substantially challenged.

The indications for surgery are considered for various levels of visual impairment. A cutoff of Snellen acuity of 20/50 or worse is based on common State laws requiring better vision for drivers of motor vehicles.

Visual Disability With a Snellen Acuity of 20/50 or Worse. Cataract surgery is justified and appropriate when the subjective, objective, and educational criteria are met.

Subjective: The subjective criterion in this case is that the ability to carry out needed or desired activities is impaired. The patient's decision depends on his or her assessment of visual disability (e.g., impact on driving, reading, watching television, and special occupational or avocational needs) and perception of the impact of the disability on lifestyle (e.g., loss of independence, loss of income).

Objective: The objective criterion is based on the best level of visual acuity. The best correctable visual acuity in the affected eye is 20/50 (Snellen) or worse and the cataract is responsible for this. The patient's medical and mental health should permit surgery to be performed safely.

Educational: The patient should be educated about the risks and benefits of cataract surgery, including treatment alternatives. The patient determines if the expected reduction in the disability outweighs the potential risk, cost, and inconvenience of surgery.

Visual Disability With a Snellen Acuity of 20/40 or Better. Cataract surgery is justified and appropriate when all of the following criteria are met.

Subjective: The subjective criterion for justifying surgery for this level of disability is also that the ability to carry out needed or desired activities is impaired. There are three aspects of this to consider:

- The patient's own assessment of visual disability (e.g., impact on driving, viewing television, and special occupational or avocational needs) and disability at near (e.g., reading, occupational activities requiring near vision).
- The patient's perception of the impact of the disability due to the cataract on his or her lifestyle.
- The patient's complaints of disabling glare. Occasionally, patients with cataract present with the complaint of disabling glare. These patients will often see more poorly in daylight conditions, so their visual complaints will be inconsistent with the visual acuity measured in a darkened room. When this appears to be the case, the assessment of visual function under conditions of ambient sunlight will often reveal the existence of this functional complaint and the reasons for it. The differences between measured acuity in a darkened room (and high-contrast chart) and that with ambient light producing glare and reduction of functional acuity need to be documented. When such a verifiable, reproducible loss of vision can be documented, mimicking the patient's complaints, the patient can be considered for cataract surgery. The application of glare testing and contrast sensitivity testing is discussed in Chapter 4.

As a general rule, the better the Snellen acuity is, the greater the need is for verification and documentation of functional disability. When visual acuity is 20/40 or better, the risk relative to the potential benefit of surgery becomes even more significant. Decreased vision and function may be documented for any of the following reasons:

- Visual disability fluctuates as a result of environmental factors (e.g., effects of glare, such as lights of oncoming cars or dim illumination).
- The patient complains of monocular diplopia or polyopia.
- Visual disparity exists between the two eyes.
- The patient needs but cannot obtain an unrestricted driving license.

Objective: The objective criterion is also based on the level of visual acuity. The best correctable visual acuity is 20/40 or better (Snellen) in the affected eye. The eye examination confirms that cataract is the limiting factor for improving visual function when other factors do not preclude improvement following surgery. The patient's medical and mental health should permit surgery to be performed safely.

Educational: The patient should be educated about the risks and benefits of cataract surgery and alternatives to surgery. In the patient with a visual acuity that is 20/40 or better, the risk of surgery relative to the expected benefit should be reemphasized to the patient. The patient determines if the expected improvement of the disability outweighs the potential risk, cost, and inconvenience of surgery.

Visual Disability Due to Cataract in the One-eyed Patient. (See also this chapter's section on second eye surgery.) A one-eyed patient is defined as one who has permanent legal blindness in one eye.

The ophthalmologist who will perform the surgery has the obligation to inform and educate the patient as to the risk of total blindness when the potential benefits of cataract surgery are considered. The same criteria apply for both levels of visual disability. The worse the vision is in the fellow eye, the greater the need is for caution when cataract surgery is considered.

Other Indications for Cataract Removal. There are two other indications for cataract removal:

- Lens-induced disease.
- The need to visualize the fundus.

As documented in the published literature, cataract removal may be necessary in the presence of lens-induced diseases (e.g., phacomorphic glaucoma, phacolytic glaucoma). Because of sight-threatening and eye-threatening complications, the need for cataract extraction may be urgent.

It is necessary to visualize the fundus to manage adequately ocular conditions that would otherwise lead to worse or permanent visual loss in an eye that has the potential for sight (e.g., the patient has diabetes, with significant risk of reduced visual acuity from diabetic retinopathy requiring management through visualization for diagnosis or clear media laser therapy) or when other special investigations demonstrate intraocular pathology for which further attention is important and clear media are required.

Recommendations for Research

The panel recommends that research be directed toward a better understanding of functional impairment due to cataract to elucidate more precisely the appropriate indications for cataract surgery.

Contraindications for Surgery

Surgery should not be performed solely to improve vision under the following circumstances:

- The patient does not desire surgery.
- Glasses or visual aids provide satisfactory functional vision.
- The patient's lifestyle is not compromised.
- The patient is medically unfit.

Preoperative Medical Evaluation

Background

Most patients undergoing cataract surgery are elderly persons, a population with a high prevalence of concurrent medical problems such as coronary artery disease, cerebrovascular disease, hypertension, diabetes mellitus, dementia, arrhythmias, chronic obstructive pulmonary disease, alcoholism, thromboembolic disease requiring anticoagulant therapy, and nutritional problems. In addition, these patients often have unique and commonly dysfunctional problems of aging, including situational difficulties and other problems, such as arthritis, as well as psychosocial, economic, and nutritional difficulties. Functional problems and their causes (often multiple and complex), defined as difficulties that interfere with daily routines, are often unappreciated when conventional histories and physical examinations are done. This part of the guideline addresses the appropriate preoperative medical and general evaluation of patients undergoing cataract surgery.

Literature Review

Methods. A literature review was performed to identify articles with information on the preoperative medical and general evaluation of patients undergoing cataract surgery. In addition to the literature found in the National Library of Medicine search concerning preoperative testing and evaluation, the relevant literature relating to preventive health measures, especially in the elderly, and some applicable literature concerning nonophthalmologic surgery were reviewed in preparation of the guideline. (For a full description of the literature review, see Appendix I in the *Guideline Report.*)

Results. All the articles identified from the National Library of Medicine literature search, reviewers, and other interested parties have serious methodologic flaws. Eight (Applegate, Miller, Elam et al., 1987; Backer, Tinker, Robertson et al., 1980; Fisher and Cunningham, 1985; Hardesty, 1989; Maltzman, Cinotti, and Calderone, 1981; McMahan, 1988; Quigley, 1974; Stone, Kline, and Sklar, 1985) provided data on the value of the medical preoperative evaluation of patients with cataract. None addressed cost-benefit issues. Most are retrospective studies of patient cohorts who had undergone cataract surgery and thus were sufficiently healthy to have tolerated it. None mentioned the findings on health status of patients who had not undergone surgery. There is, thus, scant published information from which conclusions can be drawn and on which irrefutable recommendations about the preoperative medical evaluation can be based.

Question 1: Is there evidence to support or refute a specific association between short-term medical outcome in the postoperative period and the preoperative medical evaluation of the patient (physical

examination, electrocardiogram, chest x ray, complete blood count, other)?

Comprehensive recommendations about preventive health screening were made by the U.S. Preventive Services Task Force (1989), the American College of Physicians (1981 and 1987), the American Cancer Society (1988), the American Geriatrics Society (1989), the National Institutes of Health (National Cholesterol Education Program, 1988; National Institutes of Health, 1988; 1988 Joint National Committee, 1988), and the Canadian Task Force on the Periodic Health Examination (1989 and 1991). These preventive care guidelines were recently summarized in a comprehensive paper by Hayward and associates (Hayward, Steinberg, Ford et al., 1991).

There appears to be substantial variability among different institutions in the preoperative medical evaluation of cataract patients. The author of one textbook recommends that a full battery of screening tests be obtained (e.g., complete blood count, electrolytes, renal function test, urinalysis, electrocardiogram, and chest x ray) because of the advanced age and multiple medical problems of these patients (Hardesty, 1989). Others advocate reducing the routine preoperative testing and report no significant harm in making such reductions in patients undergoing a variety of surgical procedures, all of which have a greater risk of complications than cataract surgery (Blery, Charpak, Szatan et al., 1986; Kaplan, Boeckmann, Roizen et al., 1982; Kaplan, Sheiner, Boeckmann et al., 1985; Lawrence, Gafni, and Gross, 1989; Roizen, 1988). In particular, the usefulness of a routine preoperative urinalysis (Lawrence, Gafni, and Gross, 1989) and chest x ray (Charpole, Blery, Chastang et al., 1988; Roberts, Fowkes, Ennis et al., 1983; Rucker, Frye, and Staten, 1983) has been questioned, and the benefit of preoperative pulmonary function testing seems to be restricted to a very small group of surgical patients that does not include cataract surgery patients (American College of Physicians, 1990; Zibrack, O'Donnell, and Marton, 1990).

Concurrent medical problems are especially common in patients undergoing cataract surgery. A retrospective study by Maltzman and associates (Maltzman, Cinotti, and Calderone, 1981) of 200 patients who underwent cataract surgery found that only 51 patients (25.5 percent) had no disorders other than cataracts. Previously known chronic ailments were present in 137 (68.5 percent), and 44 (22 percent) had 58 newly discovered disorders. The medical ailments present in the patients included cardiac disorders (7 percent), diabetes mellitus (4 percent), hypertension (3.5 percent), pulmonary disease (3.5 percent), anemia (2.5 percent), inguinal hernia (2 percent), hepatomegaly (2 percent), and other abnormalities (venous insufficiency, urinary tract infection, electrolyte imbalance in 4.5 percent). Each of the five preoperative tests (chemistry profile, complete blood count, urinalysis, x ray, electrocardiogram) performed on this group of patients appeared equally important in uncovering new disease. The authors believed that none of the preoperative medical tests could have

been eliminated to reduce the cost of testing without missing some of the medical disorders. In addition to being retrospective, the study has several methodologic flaws that weaken its scientific strength. A number of patients were excluded from the study because threatening preadmission findings caused their surgery to be canceled, thus biasing the study toward making preadmission testing appear less important than it actually was in detecting unknown disease. The importance of preoperative testing is actually understated by the data in this study. The age of the patients in this study was not mentioned.

In another retrospective study, 100 consecutive patients who averaged 75 years of age and who had undergone cataract extraction in the hospital were retrospectively reviewed (Fisher and Cunningham, 1985). Laboratory investigation included a complete blood count, chemistry profile, urinalysis, chest x ray, electrocardiogram, and other tests as indicated by the history and physical examination. One or more significant preexisting medical conditions were found in 84 percent of the patients. Conditions included hypertension (47 percent), diabetes mellitus (16 percent), congestive heart failure (10 percent), and significant pulmonary disease, including chronic obstructive pulmonary disease, chronic bronchitis, and interstitial fibrosis (7 percent). Significant atherosclerosis or arteriosclerotic heart disease, defined as previous myocardial infarction, angina, peripheral vascular insufficiency, occlusive carotid disease, atherosclerotic valvular disease, or a history of transient ischemic attacks or strokes, was found in 38 percent of the patients. The authors of this study believe that all patients undergoing cataract extraction should have a thorough preoperative medical evaluation. Many patients (78 percent) were taking one or more medications, including coumadin (4 percent). In addition to being retrospective, the study has several methodologic flaws that weaken its scientific strength. Patients excluded from the study because preadmission findings caused their surgery to be canceled were not included, thus biasing the study toward making preadmission testing appear less important than it actually was in detecting unknown disease. The importance of preoperative testing is thus also understated by the data in this study.

A study by Blery and associates (Blery, Charpak, Szatan et al., 1986) from a teaching hospital in France is informative in this regard. Selective ordering of 13 preoperative tests (blood typing, antibody screen, hemoglobin, prothrombin time, partial thromboplastin time, bleeding time, platelet count, electrolytes, creatinine, blood-urea-nitrogen (BUN), glucose, chest x rays, and electrocardiogram) was studied in 3,866 consecutive patients undergoing surgery under general or regional (but not local) anesthesia over a 1-year period between 1983 and 1984. Almost half the patients underwent minor surgical procedures defined as potentially bloodless operations, most of which were done on an elective basis. Although cataract surgery would fall into this category, the study did not specifically address cataract extraction. Preoperative testing was done

according to a protocol that accounted for the patient's clinical status and type of surgery. Routine testing was not done in patients undergoing minor surgery unless they were age 40 and over, had associated conditions, or were taking medications. For instance, an electrocardiogram was done routinely in those age 40 and over, and electrolytes, creatinine, and BUN determinations were routinely done in those over age 70. Patients with cardiovascular or pulmonary disease had chest x rays and electrocardiograms, regardless of their age, and patients with diabetes mellitus all had renal function, electrolytes, and glucose determinations. This strategy resulted in an average of about four tests for each patient in the entire group. A total of 140 patients (8 percent) in the minor surgery group experienced preoperative or postoperative morbidity, and two died after surgery. The possible value of tests that were omitted was assessed in light of events that occurred during and after surgery. The authors concluded that 0.4 percent of nonordered tests would have been potentially useful according to predetermined computerized criteria, and only 0.2 percent would actually have predicted an adverse outcome according to the opinion of the anesthesiologists participating in the study. This study has several methodologic flaws, and its generalization to cataract patients is also questionable. The study actually comprised a series of judgments resulting in very different testing of a broad variety of patients with disparate diseases. Despite the large number of patients in this study, its statistical power is uncertain, since a number of patient populations with very different characteristics were studied. For example, the level of illness was not systematically addressed. In addition, the study's design may have biased the results to favor the conclusions that were reached by the authors; the idea that computerized criteria can be established to identify laboratory tests that will predict an adverse outcome is a unique idea that itself requires validation. The anesthesiologists were not blinded to the patient's adverse outcome when they made a judgment about the laboratory testing, which may also have biased the results.

Perioperative Management of Selected Common Medical Problems: Most cataract patients are elderly, with a high prevalence of conditions associated with aging. In addition, elderly patients often take one or more potent medicines. Despite these concurrent problems, the risk of this short, very limited surgical procedure is low. The perioperative mortality of ophthalmic surgery patients overall is only 0.16 percent, and for cataract patients, it is 0.1-0.2 percent (Quigley, 1974). The incidence of serious medical complications such as myocardial infarction associated with ophthalmologic surgery under local anesthesia is less than 1 percent, even in patients with a past history of myocardial infarction.

Although the risk of serious medical complications is quite low in cataract surgery patients, concurrent medical problems frequently cause concern among ophthalmologists, anesthesiologists, internists, and other physicians involved in the management of these patients. Such concerns may lead to additional pre-, intra- and postoperative interventions that may

be associated with considerable cost and uncertain benefit. To date, optimal perioperative management of medical problems has not been defined for cataract patients specifically. Therefore, it is likely that a great deal of variation exists in current practice patterns regarding the perioperative medical management of cataract patients.

Anticoagulant drugs being taken for thromboembolic, cardiovascular, or neurologic disorders pose a special problem. The literature reflects conflicting practices during cataract surgery concerning patients taking anticoagulant drugs. A recent survey (Stone, Kline and Sklar, 1985) of 135 cataract surgeons indicated that 75 percent of the respondents withheld anticoagulation during the perioperative period, which resulted in two deaths from strokes, two additional strokes, one transient ischemic attack, a cerebral embolism in a patient with an artificial valve, a pulmonary embolus, and an episode of deep-vein thrombosis. This retrospective survey does not provide enough data about the patients, their level of disease, or how the decision was made to discontinue anticoagulant drugs to permit a critical analysis of the conclusion. Another study (McMahan, 1988) prospectively compared the outcome of 22 patients undergoing intraocular lens (IOL) implantation who were receiving anticoagulants with age-matched patients (controls) who were not receiving these drugs. After continuing anticoagulation through the surgical and postoperative period, no patient experienced clinically significant bleeding that interfered with vision. There were no retrobulbar, vitreous, or retinal hemorrhages and no elevated pressures in any anticoagulated or control patient. On the basis of these limited data, it appears that anticoagulation does not pose a substantial risk for seriously complicating ophthalmic surgery, whereas discontinuing these drugs may impart some increased risk for new thrombotic events in the patient with preexisting cardiovascular, cerebrovascular, or thromboembolic disease. The selection of controls in this study was weak, since they were matched with patients only for age and not other characteristics, such as underlying major illnesses. In addition, the study is flawed by the very small number of patients, which makes the likelihood of a type 2 error very high.

Myocardial reinfarction in the course of cataract surgery is of particular concern in the elderly patient with a past history of myocardial infarction. A retrospective study (Backer, Tinker, Robertson et al., 1980) of myocardial reinfarction after local anesthesia for ophthalmic surgery found no postoperative reinfarction or death in 195 patients who underwent 288 separate operations. The 0 percent reinfarction rate was significantly less than the 6.1 percent reinfarction rate previously reported from the same institution for 587 operations on patients with documented preoperative myocardial infarction who had general or major regional anesthesia for nonophthalmic surgery. Thus, on the basis of these limited data, it appears that ophthalmic surgery under local anesthesia and/or retrobulbar block does not pose special risks for reinfarction in the patient with a preoperative myocardial infarction. This study's major weakness is that it

selectively reports only on patients on whom surgery was done, omitting those who might have been rejected for surgery because of serious cardiac symptoms or signs or because of ominous laboratory tests. For instance, if patients with congestive heart failure or severe angina undergo surgery, the results might be different than if they had been rejected as unsuitable surgical candidates.

Preoperative Evaluation of the Elderly Patient: The majority of patients undergoing cataract surgery are elderly persons who not only have a high prevalence of multiple medical problems, but also have unique problems of aging that commonly affect their ability to function. Functional problems, defined as difficulties that interfere with daily routines, are often unappreciated when conventional histories and physical examinations are done. Functional assessment, therefore, is an integral part of geriatric care (American College of Physicians, Health and Public Policy Committee, 1988; Williams, 1990). Its importance was underscored by the Consensus Development Conference at the National Institutes of Health (1988), which stated that comprehensive geriatric assessment is effective in improving the quality of ongoing care.

Although most elderly noninstitutionalized adults are functionally competent, the percentage who need help doing everyday activities doubles with each successive decade up to age 84 and triples between ages 85 and 94 (Feller, 1983). In addition to visual dysfunction, elderly persons often have other equally severe and unrecognized functional problems resulting from hearing disorders, difficulty with arm and leg function, urinary incontinence, depression, dementia, environmental hazards, and inadequate financial and social support systems. Although there is general agreement that functional assessment is most useful when a standard, systematic approach is used to measure and record observations, there is a general lack of consensus on the best way to perform these evaluations (Williams, 1990).

One study (Applegate, Miller, Elam et al., 1987) prospectively examined the impact of cataract surgery on the functional status of 293 elderly patients undergoing cataract surgery. Patient function was evaluated by both subjective measures (everyday activities and self-report of vision-dependent activities) and objective measures (timed manual performance tests and mental status tests). With marked improvement in visual acuity, modest positive changes occurred in self-reported everyday activities and vision-dependent activities; the most marked changes occurred in objective measures of function. Mental status improved significantly 1 year after surgery, and timed manual performance improved dramatically at 4 months and 1 year. This study is sound methodologically but does not address the issue of preoperative medical testing of cataract patients. Cataract surgery was associated with better vision and improved functional status in most patients by 4 months after surgery and was maintained 1 year later.

The patient's perception of disability and self-assessment of impairment are extremely important in evaluating the impact of therapy.

A new approach to assessing functional disability was described by Tugwell and associates (Tugwell, Bombardier, Buchanan et al., 1987), who devised an instrument that has the potential to detect small, clinically important changes in function. These authors developed a new patient preference questionnaire for assessing disability that focuses only on those activities directly affected by the disability and judged to be important by the patient. This study is sound methodologically but does not address the issue of preoperative medical testing of cataract patients.

The American College of Physicians recently advocated incorporating functional status measurement into routine clinical practice (American College of Physicians, Health and Public Policy Committee, 1988). The College commissioned a group of investigators to identify the important areas in which elderly persons who are not acutely ill should be screened for functional disabilities and to develop a simple, practical, and sensible approach to the screening assessment. Lachs and associates (Lachs, Feinstein, Cooney et al., 1990) devised such an instrument. After a careful literature review, Lachs and coworkers concluded that most published instruments were impractical because they are too lengthy, require special equipment, or are not targeted to older populations. With the assistance of a panel of expert geriatricians and general internists, they developed a short, simple approach that can be used by primary health care providers to screen the functional status of elderly patients routinely. The instrument focuses on a limited number of target areas that are commonly dysfunctional but often unappreciated in the elderly when conventional histories and physical examinations are done. The instrument uses carefully selected tests of vision, hearing, arm and leg function, urinary incontinence, nutrition, mental status, depression, basic everyday activities (a term that refers to the abilities needed for independent self-maintenance in the basic functions of bathing, eating, dressing, toileting, transferring, and walking), and instrumental everyday activities (a term often used for higher levels of independent function such as cooking, shopping, and light housework) and explores potential environmental hazards and social support systems. Brief questions and easily observed tasks are used to obtain information in a short time. One of its targets is the home environment. It explores the most troublesome obstacles in mobility for elderly patients living at home: the stairs, both inside and outside. Patients are asked about potential hazards inside the home with rugs, bathtubs, and lighting. It also asks about the social support network in which the patient functions and examines the availability of care to be anticipated during a transient illness such as the postoperative period. The home environment and anticipated support network are especially important issues for patients undergoing cataract surgery. This instrument requires no special equipment and can be done by a nurse, physician, or other trained health care provider. It also suggests appropriate interventions.

Cultural, ethnic, and spiritual values should be noted, along with the individual's own assessment of the quality of life (Maltzman, Cinotti, and

Calderone, 1981). The clinician should evaluate the economic resources of the elderly person, since this often determines access to medical and personal care and influences options for living arrangements.

Question 2: Is there evidence to support or refute an association between nonmedical evaluation and preparation of the patient and outcomes? (Issues researched include psychosocial issues, patient education, patient preparation, family preparation, and home environment.)

Question 3: Is there information on cost and/or cost-benefit issues?

No articles were found addressing these questions.

Conclusions of the Panel

The evidence in the published literature is sparse. The panel reached the following conclusions by consensus:

- The preoperative medical examination and appropriate testing should be done in all patients undergoing cataract surgery, whether the surgery is done in the hospital or elsewhere and regardless of the type of anesthesia to be used.
- Preoperative medical management should be guided by the patient's age, the presence of concurrent medical illnesses, the patient's use of medicine, and the patient's relative proximity to the location where surgery is performed.
- General preventive health measures (e.g., for hypertension, diabetes, smoking, and obesity) are suggested for all, including patients who otherwise may have infrequent encounters with the health care system. The panel believes that patients have the right to know what preventive measures are effective and appropriate in these circumstances, although they may choose to not take advantage of them.
- The preoperative medical evaluation should include screening for functional disability. Elderly patients should receive special screening of functional status, and particular attention should be given to the socioeconomic problems imposed by aging. This recommendation is in keeping with the panel's stated ultimate goal of improving the patients' overall long-term health and functional ability and the maintenance of autonomy.
- The panel agreed that the patient (or the patient and the ophthalmologist) can choose to have the preoperative medical evaluation for cataract surgery performed by a generalist or an appropriate subspecialist. This should be considered a separate service from the preoperative ophthalmologic evaluation in regard to the global surgery concept for cataract surgery.
- Areas of special importance to the individual such as cultural ethics and spiritual values should be taken into consideration before surgery, along

with the individual's own assessment of the quality of life, for optimal preparation of the patient for surgery and recovery.
- The economic resources of the elderly person should be evaluated before surgery, since this often determines access to medical and personal care and influences options for living arrangements.
- Although the data are sparse, anticoagulation does not appear to pose a substantial risk for seriously complicating ophthalmic surgery, whereas discontinuing these drugs may impart some increased risk for new thrombotic events in the patient with preexisting cardiovascular, cerebrovascular, or thromboembolic disease.

In light of the sparse published literature available on this topic, the panel is unable to make explicit recommendations regarding the extent of the general medical evaluation and testing that should be done prior to cataract surgery. The panel recognizes, however, that this is an issue that cuts across the whole field of elective surgery and patient care.

Accordingly, the panel recommends that AHCPR develop guidelines for preoperative general medical evaluation and general medical testing of patients undergoing nonemergency surgery, including cataract surgery. Until such guidelines are established, the panel agreed that it should adopt a commonsense approach to preoperative evaluation that would be sensitive to the medical judgment of a prudent physician evaluating an individual patient. Unfortunately, no consensus exists concerning the explicit goal of the preoperative medical evaluation of the patient scheduled for cataract surgery. However, the Preventive Services Task Force (1989) has recommended routine preventive measures for use in primary care settings that may be applicable to patients undergoing surgical procedures who do not ordinarily receive routine care. The preoperative medical evaluation can either be narrowly viewed as an occasion to evaluate the patient's health solely as it pertains to cataract surgery or be approached in the broader context of a unique opportunity to evaluate the patient fully and to diagnose potentially serious health, functional, and social problems unrelated to cataract surgery. The broader view is consistent with an ultimate goal of improving the overall long-term health and well-being of patients undergoing cataract surgery, instead of restricting the focus to improving vision. The panel favored the broader view but acknowledged that preventive health screening is a secondary issue that was not part of the panel's charge.

Recommendations for Research

Preoperative testing of cataract patients requires further study. Prospective studies should be designed and nationally funded to test the cost effectiveness of complete medical evaluation insofar as it prevents untoward intraoperative and postoperative events, uncovers previously unrecognized and treatable disease, and effectively disseminates preventive health measures.

Anesthesia

Anesthesia for cataract surgery can be either general or local.

Background

The choice and management of anesthesia technique may have a direct effect on the success of cataract surgical outcome. Many cataract patients are elderly, with multiple medical problems, particularly pulmonary and circulatory, and thus are at increased risk for morbidity during the perioperative period.

Anesthesia decisions that may influence outcome include the choice of general anesthesia vs. regional anesthesia with sedation and the choice from a variety of retrobulbar or peribulbar local anesthesia techniques available. The training and experience of the practitioner may influence the results and complication rates.

Finally, consideration must be given to the costs and benefits of various anesthetic management plans.

Literature Review

Methods. The purpose of the literature review was to identify and review those articles that might provide a sound clinical and scientific basis for recommendations for anesthesia management of the cataract patient. The literature review was limited to recent (1975-90) articles that addressed nine specific search questions relating to anesthesia and cataract surgery. (For a full description of the literature review process, see Appendix J in the *Guideline Report.*)

Results. A preliminary literature search identified 87 potentially relevant articles. Seven additional articles were identified from various sources. Of these 94 articles identified, only 9 were found to be relevant to the questions addressed by the panel. These nine articles underwent indepth methodologic and content review. The results of the literature review are as follows and are summarized in Attachment 7 at the end of this document.

Question 1. Is there evidence to support or refute an association between visual outcome of cataract surgery and the choice of general vs. local anesthesia?
Question 2: Is there evidence to support or refute an association between visual outcome of cataract surgery and the choice of local anesthesia, retrobulbar vs. peribulbar?
Question 3: Is there evidence to support or refute an association between visual outcome of cataract surgery and the identity and credentials of the individual monitoring the patient?
Question 4: Is there evidence to support or refute an association between visual outcome of cataract surgery and the identity and

credentials of the individual administering retrobulbar injection? (Consider anesthesiologist, nurse anesthetist, ophthalmologist, technician, other.)

No evidence was found in the literature addressing these questions.

Question 5: Is there evidence to support or refute an association between anesthesia morbidity and choice of general vs. local anesthesia?

One article (Karhunen and Orko, 1981) found that nausea and vomiting may be less likely after local than general anesthesia. This article had significant methodologic flaws.

Question 6: Is there evidence to support or refute an association between anesthesia morbidity and choice of local anesthesia, retrobulbar vs. peribulbar?

Three articles (Hamilton, Gimbel, and Strunin, 1988; Weiss and Deichman, 1989; Whitsett, Balyeat, and McClure, 1990) appeared to indicate that a peribulbar technique can be as effective as retrobulbar, but with fewer complications. Another article (Whittpen, Rapoza, Sternberg et al., 1986) suggested that patients receiving 4-percent lidocaine by retrobulbar injection were at greater risk of respiratory arrest than patients receiving 2-percent preparation. All studies were flawed by general methodologic deficiencies that made the conclusions difficult to interpret, though they were intuitively appealing.

Question 7: Is there evidence to support or refute an association between anesthesia morbidity and the identity and credentials of the individual monitoring the patient? (Consider anesthesiologist, nurse anesthetist, operating ophthalmologist, other.)

One article (Meyers, 1979) suggested that there was an increased incidence of severe cardiovascular complications in unmonitored patients. A number of methodologic flaws in this retrospective evaluation of a clinical series rendered the study's conclusions uncertain and difficult to interpret.

Question 8: Is there evidence to support or refute an association between anesthesia morbidity and the identity and credentials of the individual administering retrobulbar or peribulbar injection? (Consider anesthesiologist, nurse anesthetist, ophthalmologist, technician, other.)

Question 9: Is there information on cost and/or cost-benefit issues?

No articles were found in the literature addressing these questions.

Conclusions From the Literature Review

Of the 94 articles identified by the National Library of Medicine computer search and other sources, only 9 met the search criteria and were further considered by content and methodologic reviewers for detailed

analysis. Results of the review of these articles revealed that only three were randomized controlled trials. The remainder were either uncontrolled trials or clinical series. There were no well-designed prospective studies that compared general anesthesia vs. local anesthesia and anesthesia morbidity. No studies associated morbidity with the identity of the person monitoring or administering the local anesthesia injection. Two articles mentioned cost effectiveness in passing, but there was no study specifically analyzing in detail the costs and benefits of general vs. local anesthesia.

Only two articles (Redmond and Dallas, 1990; Smith, 1990) mentioned visual outcome. There was no information to associate visual outcome with choice of general or local anesthesia. Most articles noted complications of surgery or anesthesia but were of poor quality.

Recommendations for Care

The panel concurred that the choice of general or local anesthesia may affect visual outcome indirectly (i.e., through the effects of nausea, vomiting, or coughing after general anesthesia or sudden movement during local anesthesia) or directly. On balance, properly managed local anesthesia is simpler than general anesthesia, especially in patients with significant cardiac or pulmonary problems. Special monitoring techniques may be advisable in these patients. The panel concurred that the use of modern monitoring techniques is appropriate in cataract surgery, given the age of the patients and the high incidence of associated medical problems. Good monitoring might affect visual outcome indirectly if it prevents sustained hypertension, hypotension, or hypoxia.

The panel further believes that monitored anesthesia care by qualified anesthesia personnel is appropriate because the ophthalmologist is fully occupied in the surgical technique and therefore unable to deal with emergencies in a timely manner. Monitored anesthesia care includes physiologic monitoring with life-support systems available. The panel concurred that the administration of local anesthesia for cataract surgery is a skilled procedure and should be performed by an ophthalmologist or by another appropriately trained professional who has demonstrated competence in these techniques.

The panel agreed that there is a lack of studies in the literature addressing issues surrounding the administration of anesthesia for cataract surgery. The panel reached by consensus the following recommendations for care:

- Properly managed local anesthesia is preferred to general anesthesia and is appropriate unless precluded by extreme patient anxiety that does not respond to counseling or sedation, inability of the patient to cooperate with the surgical team, inability to provide satisfactory local anesthesia, known allergy to local anesthetic medications, and the presence of disorders that are best managed under general anesthesia (severe back pain, postural problems, etc.).

- Given the age of patients undergoing cataract surgery and the high incidence of associated medical problems, monitored anesthesia care provided by an anesthesiologist or anesthetist is justified and appropriate.
- Monitored anesthesia care should include the use of the following monitoring techniques: electrocardiogram, pulse oximetry, blood pressure, and respirations.
- The use of sedation drugs (reversible and with reduced side effects) is appropriate to minimize pain and discomfort while local anesthesia is being administered.
- Local anesthesia may be induced by the retrobulbar or peribulbar technique. Each has its own set of complications and advantages. The literature search did not identify evidence that one method was superior to others.
- The administration of peribulbar and retrobulbar anesthesia is a skilled procedure.
- It is in the best interest of the patient to have the safest local anesthesia possible administered by an individual fully trained in the procedure to be used.
- Because of the potential for extraocular complications (e.g., brain-stem anesthesia), peribulbar and retrobulbar anesthesia should be administered only to properly monitored patients with intravenous access established. There should be access to oxygen with assisted respirations via mask ventilation apparatus if necessary.

The panel also recommends that, in the patient's best interest, requirements for clinical competence to perform retrobulbar or peribulbar anesthesia be established to include training; supervision; knowledge of the appropriate anatomy, physiology, and pharmacology; and the ability to handle complications and consequences.

Recommendations for Research

The panel recommends that research be undertaken on unresolved questions concerning the impact of anesthesia on the outcome of cataract surgery, including cost and cost-benefit analyses.

Surgical Techniques and Complications

Background

The dramatic revolution in cataract surgery over the last 15 years has been spearheaded by the adoption of microsurgical techniques. This includes the transition to the extracapsular cataract extraction (ECCE) procedure; the development of safe, effective IOLs; and the placement of the IOL behind the iris. The widespread acceptance of IOLs permitted satisfactory visual rehabilitation of patients with monocular cataracts who

formerly would have been dependent on aphakic contact lenses. It is generally acknowledged that with these changes in technique, postoperative visual rehabilitation has improved to the point where surgical intervention is now appropriate at a much earlier stage of visual disability than had previously been possible.

Over the same period, modification of the surgical technique has continued on a variety of fronts. Most notable has been the introduction of phacoemulsification (PE) as a method of lens extraction. PE raises the expectation of enhanced safety and more rapid rehabilitation because of the reduced wound size needed. Alternative lens designs are also being explored to accommodate this decreased wound size and in an attempt to provide clear vision at both distance and near.

In this section, the type of surgical techniques (ECCE vs. PE) is considered in the context of effectiveness and complication rates. Lens design, secondary lens implantation, and other technical innovations are not within the scope of this guideline.

Literature Review

Methods. The purpose of the literature review was to identify and review the literature that contained information regarding surgical techniques and complications. The questions used to define potentially relevant articles are detailed in the Results section.

Results. The systematic literature search identified 6,113 potentially relevant articles. Of these, 100 met the eligibility criteria established for this review. All of these articles underwent indepth methodologic and content reviews. The results of the literature review are as follows and are summarized in Evidence Tables K-1 to K-26 in Appendix K in the *Guideline Report.*

Overall, 57 studies examined visual acuity, 20 examined astigmatism, and 83 examined complications. On a study-specific basis, 4 studies examined only visual acuity, 31 examined only complications, 10 examined only astigmatism, 43 examined visual acuity and complications, none examined complications and astigmatism, and 7 examined visual acuity, complications, and astigmatism.

Among all the studies that examined visual acuity, the number of eyes studied ranged from 17 to 1,588. (The largest number of eyes studied by procedure was 756 for PE and 1,588 for ECCE.) Among all the studies that examined astigmatism, the number of eyes studied ranged from 50 to 503. (The largest number of eyes studied by procedure was 397 for PE and 503 for ECCE.) Among all the studies examining complications, the number of eyes studied ranged from 41 to 22,791. (The largest number of eyes studied by procedure was 2,704 for PE, 1,588 for ECCE, and 22,791 for a mixed group of PE and ECCE for which complications were reported for the entire group and not according to type of procedure used.)

The following is a summary of information on the principal outcomes and complications of cataract surgery. The data presented are exclusively from clinical series and observational studies. None of the studies that met the inclusion criteria involved random allocation of patients to various surgical procedures. Additionally, case mix (e.g., frequency of other significant eye disease in the study population), length of followup time, and definitions for specific complications varied tremendously by study. Therefore, great caution must be exercised both in examining specific rates as well as in pooling data across studies. Moreover, these methodologic limitations render any comparisons of outcomes between procedures (e.g., PE vs. ECCE) hazardous.

Question 1: Is there evidence that visual acuity after final refraction is better, no different, or worse when a cataract is extracted via standard ECCE vs. PE?

Of the articles that met the inclusion criteria, 57 examined visual acuity (Acheson, McHugh, and Falcon, 1988; Allen and Zhang, 1987; Azen, Hurt, Steel et al., 1983; Barrett, Beasley, Lorensetti et al., 1987; Barrett, Constable, and Steward, 1986; Brint, Ostrick, and Bryan, 1991; Cheng, 1987; Cinotti, Fiore, Maltzman et al., 1988; Cunliffe, Flanagan, George et al., 1991; Davison, 1984; Faulkner, 1987; Galand, Van Oye, Budo et al., 1985; Hara, 1986; Heslin and Guerriero, 1984; Komatsu, Kanagami, and Shimizu, 1989; Kooner, Cooksey, Perry et al., 1988; Kraff and Sanders, 1982; Kraff, Sanders, and Jampol, 1982; Kraff, Sanders, and Lieberman, 1983; Kraff, Sanders, Jampol et al., 1984 and 1985; Kratz, Mazzocco, and Davidson, 1979; Kratz, Mazzocco, Davidson et al., 1981a and 1981b; Levy and Pisacano, 1988; Liesegang, Bourne, and Ilstrup, 1990; Littlewood and Constable, 1985; Loh, Chew, Phua et al., 1985; Markoff, Levin, and Behar, 1985; Masket, 1989; McCaffrey and Lusby, 1986; Menapace, Skorpik, and Wedrich, 1990; Moschos, 1988; Naeser, Rask, and Hansen, 1986; Naylor and Sutton, 1989; Neumann and Cobb, 1989; Neumann, McCarty, Sanders et al., 1989; Noble, Hayward, and Huber, 1990; Pallin, 1987; Pedersen, 1990; Percival, 1987a and 1987b; Rich, Condon, and Percival, 1988; Ridgway, 1985; Shepherd, 1989a; Shimizu, 1988; Silvestri, Shepherd, and Johnston, 1989; Simcoe, 1981; Southwick and Olson, 1984; Stark, Maumenee, Datiles et al., 1983; Steinert, Brint, White et al., 1991; Story, 1988; Straatsma, Meyer, Bastek et al., 1983; Van Oye, Budo, Galand et al., 1986; Watts, 1986; Woodhams, Maddox, Hunkeler et al., 1984; Wright, Wilkinson, Balyeat et al., 1988). Visual acuity data were limited by a lack of documentation of preoperative data, including both visual acuity and documentation of ocular comorbid conditions that might limit postoperative acuity.

Thirty-three of the 57 provided data on the percent of eyes without preexisting eye disease that achieved visual acuity of 20/40 or better (Acheson, McHugh, and Falcon, 1988; Allen and Zhang, 1987; Barrett, Beasley, Lorensetti et al., 1987; Barrett, Constable, and Steward, 1986;

Brint, Ostrick, and Bryan, 1991; Cheng, 1987; Cunliffe, Flanagan, George et al., 1991; Galand, Van Oye, Budo et al., 1985; Heslin and Guerriero, 1984; Komatsu, Kanagami, and Shimizu, 1989; Kratz, Mazzocco, and Davidson, 1979; Kratz, Mazzocco, Davidson et al., 1981b; Levy and Pisacano, 1988; Markoff, Levin, and Behar, 1985; Masket, 1989; McCaffrey and Lusby, 1986; Menapace, Skorpik, and Wedrich, 1990; Neumann, McCarty, Sanders et al., 1989; Pallin, 1987; Pedersen, 1990; Percival, 1987a and 1987b; Rich, Condon, and Percival, 1988; Shepherd, 1989a; Shimizu, 1988; Silvestri, Shepherd, and Johnston, 1989; Southwick and Olson, 1984; Stark, Maumenee, Datiles et al., 1983; Steinert, Brint, White et al., 1991; Story, 1988; Straatsma, Meyer, Bastek et al., 1983; Van Oye, Budo, Galand et al., 1986; Wright, Wilkinson, Balyeat et al., 1988). Of these 33 studies, 31 (94 percent) reported that greater than 90 percent of eyes achieved acuity of 20/40 or better (Allen and Zhang, 1987; Barrett, Beasley, Lorensetti et al., 1987; Barrett, Constable, and Steward, 1986; Brint, Ostrick, and Bryan, 1991; Cheng, 1987; Cunliffe, Flanagan, George et al., 1991; Galand, Van Oye, Budo et al., 1985; Heslin and Guerriero, 1984; Komatsu, Kanagami, and Shimizu, 1989; Kratz, Mazzocco, and Davidson, 1979; Kratz, Mazzocco, Davidson et al., 1981b; Levy and Pisacano, 1988; Masket, 1989; Markoff, Levin, and Behar, 1985; McCaffrey and Lusby, 1986; Menapace, Skorpik, and Wedrich, 1990; Neumann, McCarty, Sanders et al., 1989; Pallin, 1987; Pedersen, 1990; Percival, 1987a and 1987b; Rich, Condon, and Percival, 1988; Shepherd, 1989a; Shimizu, 1988; Southwick and Olson, 1984; Stark, Maumenee, Datiles et al., 1983; Steinert, Brint, White et al., 1991; Story, 1988; Straatsma, Meyer, Bastek et al., 1983; Van Oye, Budo, Galand et al., 1986; Wright, Wilkinson, Balyeat et al., 1988). The results of these 33 studies are summarized in Table 5-1.

Table 5-1. Visual Acuity Following Cataract Surgery

Percent of Eyes Reported To Be 20/40 or Better Postoperatively	Number (Percent) of Studies
≥80	33 (100%)
≥90	31 (94%)
≥95	23 (70%)
≥98	12 (36%)
100	6 (18%)

Source: Compiled from 57 articles, listed in the text, that addressed visual acuity.

These results emphasize the excellent visual results that are expected in patients without significant ocular comorbidity.

Question 2: Is there evidence that the time to final refraction is shorter, no different, or longer when a cataract is extracted via standard ECCE vs. PE?

One controlled study (Heslin and Guerriero, 1984) suggested that the time to final refraction was 8 days shorter for PE vs. ECCE. Studies available for the preparation of this document do not permit a conclusion to be drawn that differences in visual acuity at time of final refraction exist between PE and ECCE.

Question 3: Is there evidence that the incidence of occurrence of more than 2 diopters of astigmatism at the time of final refraction is greater, the same, or less when a cataract is extracted via standard ECCE vs. PE?

Twenty articles examined astigmatism (Axt, 1987; Brint, Ostrick, and Bryan, 1991; Brown and Sparrow, 1988; Cory, 1989; Davison, 1984; Dixon, 1989; Gills and Sanders, 1991; Heslin and Guerriero, 1984; Jampel, Thompson, Baker et al., 1987; Kraff and Sanders, 1982; Maltzman, Cinotti, Horan et al., 1983; Masket, 1985 and 1990; Moschos, 1988; Naeser, Rask, and Hansen, 1986; Neumann, McCarty, Sanders et al., 1989; Pallin, 1987; Parker and Clorfeine, 1989; Shepherd, 1989a; Woodhams, Maddox, Hunkeler et al., 1984). Studies on residual postoperative astigmatism were limited methodologically by inconsistent reporting of preoperative astigmatism and the reporting of summary data for entire surgical populations, thereby not permitting the actual comparison of preoperative and postoperative astigmatism for individual patients. Additionally, there was extreme variation in the duration of time after surgery for which levels of astigmatism were reported. A commonly reported target for this outcome is a degree of astigmatism of less than or equal to 2 diopters postoperatively. Of 12 studies reporting on this target (Axt, 1987; Brint, Ostrick, and Bryan, 1991; Brown and Sparrow, 1988; Cory, 1989; Davison, 1984; Jampel, Thompson, Baker et al., 1987; Masket, 1985 and 1990; Moschos, 1988; Parker and Clorfeine, 1989; Shepherd, 1989b; Woodhams, Maddox, Hunkeler et al., 1984), 6, or 50 percent (Axt, 1987; Brown and Sparrow, 1988; Masket, 1985 and 1990; Parker and Clorfeine, 1989; Shepherd, 1989a) reported that greater than 90 percent of eyes had less than 2 diopters of astigmatism. The remaining six studies (Brint, Ostrick, and Bryan, 1991; Cory, 1989; Davison, 1984; Jampel, Thompson, Baker et al., 1987; Moschos, 1988; Woodhams, Maddox, Hunkeler et al., 1984) reported that at least 70 percent of the eyes had less than 2 diopters of astigmatism. Three of the four controlled studies (Heslin and Guerriero, 1984; Kraff and Sanders, 1982; Neumann, McCarty, Sanders et al., 1989) suggest that the change in astigmatism is less for PE than for ECCE. In the remaining study (Pallin, 1987), the change in astigmatism was not significantly different. These findings are consistent with the hypothesis that the absolute level of postoperative astigmatism decreases with the size of the surgical wound, since smaller incisions are typically used with PE vs. ECCE. However, these studies do not address whether the measured differences are of clinical significance to patients. Thus, available studies do not permit a conclusion to be drawn

that clinically significant differences in astigmatism exist between PE and ECCE.

Question 4: Is there evidence that the incidence of certain ophthalmologic complications is greater, the same, or less when a cataract is extracted via standard ECCE vs. PE?

Eighty-three articles addressed rates of other complications (Acheson, McHugh, and Falcon, 1988; Allen and Zhang, 1987; Arnott and Condon, 1985; Arnott, Grindle, and Krolman, 1988; Azen, Hurt, Steel et al., 1983; Barrett, Beasley, Lorensetti et al., 1987; Barrett, Constable, and Steward, 1986; Born and Ryan, 1990; Bukelman, Hoffman, and Oliver, 1987; Cheng, 1987; Cinotti, Fiore, Maltzman et al., 1988; Coonan, Fung, Webster et al., 1985; Cunliffe, Flanagan, George et al., 1991; David, Tessler, Yagev et al., 1990; Davison, 1984 and 1988; Frezzotti and Caporossi, 1990; Galand, Van Oye, Budo et al., 1985; Hansen, Naeser, and Rask, 1987; Harris and Kogan, 1981; Heslin and Guerriero, 1984; Kattan, Flynn, Pflugfelder et al., 1991; Komatsu, Kanagami, and Shimizu, 1989; Kooner, Cooksey, Perry et al., 1988; Kooner, Dulaney, and Zimmerman, 1988; Kraff and Sanders, 1982 and 1990; Kraff, Sanders, and Jampol, 1982; Kraff, Sanders, Jampol et al., 1984 and 1985; Kraff, Sanders, and Lieberman, 1983; Kratz, Mazzocco, and Davidson, 1979; Kratz, Mazzocco, Davidson et al., 1981a and 1981b; Levy and Pisacano, 1988; Liesegang, Bourne, and Ilstrup, 1985 and 1990; Littlewood and Constable, 1985; Loh, Chew, Phua et al., 1985; Markoff, Levin, and Behar, 1985; Maynor, 1983; McCaffrey and Lusby, 1986; Menapace, Skorpik, and Wedrich, 1990; Milauskas, 1987 and 1990; Moisseiev, Bartov, Schochat et al., 1989; Moschos, 1988; Naeser, Nielsen, and Hansen, 1990; Naeser, Rask, and Hansen, 1986a and 1986b; Naylor and Sutton, 1989; Naylor, Sutton, Morrell et al., 1989; Neumann and Cobb, 1989; Neumann, McCarty, Sanders et al., 1989; Nishi, 1986; Noble, Hayward, and Huber, 1990; O'Donnell and Santos, 1985 and 1990; Pedersen, 1990; Percival, 1987a and 1987b; Raines, Corridan, and O'Neill, 1989; Rich, Condon, and Percival, 1988; Ridgway, 1985; Sellman and Lindstrom, 1988; Severin and Severin, 1988b; Sheets, 1987; Silvestri, Shepherd, and Johnston, 1989; Simcoe, 1981; Simel, 1982; Smith, Stark, Maumenee et al., 1987; Southwick and Olson, 1984; Stark, Maumenee, Datiles et al., 1983; Steinert, Brint, White et al., 1991; Sterling and Wood, 1986; Story, 1988; Straatsma, Meyer, Bastek et al., 1983; Stur, Grabner, and Dorda, 1984; Taylor, Sachs, and Stern, 1984; Van Oye, Budo, Galand et al., 1986; Watts, 1986; Woodhams, Maddox, Hunkeler et al., 1984; Wright, Wilkinson, Balyeat et al., 1988). Although there was considerable variation among all studies in the rates of five major clinical complications, the rates obtained from the studies with the largest sample sizes are as shown in Table 5-2.

Available data in the published literature do not permit reasonable conclusions to be drawn that differences in the rates of these major

Table 5-2. Complications of Cataract Surgery

Complication	Rate (Percent)
Bullous keratopathy	<0.3
Malposition or dislocation of the intraocular lens	<1.0
Endophthalmitis (intraocular infection)	<0.3
Retinal detachment	<1.0
Clinically significant cystoid macular edema (postoperative swelling of the central retina)	<3.0

Source: Compiled from 83 articles, listed in the text, that addressed rates of complications.

complications exist between PE and ECCE. This is also true for other complications, including anterior chamber hemorrhage, hypopyon, chronic uveitis, iris trauma, increased open-angle intraocular pressure (IOP), increased closed-angle IOP, PSC opacification, zonular or posterior capsule rupture, loss of nuclear fragment into vitreous, vitreous hemorrhage, choroidal hemorrhage, retinal ischemia or infarction, angiographically proven cystoid macular edema, optic neuropathy, and ptosis.

Question 5: Does the literature provide data concerning the impact of cataract surgery on overall function of the patient?

No articles that met the inclusion criteria examined changes in visual function, as measured by everyday activities. Of these, one article (Masket, 1989) examined changes in contrast sensitivity and glare disability, which are outcomes related to visual function. Nine other articles (Applegate, Miller, Elam et al., 1987; Bernth-Petersen, 1981; Donderi and Murphy, 1983; Elam, Graney, Applegate et al., 1988; Hilbourne, 1975; Hill, 1982; Immonen, Tuominen, and Raivo, 1988; OCTET, 1987; O'Malley, Newmark, Rothman et al., 1989) that examined visual function or health status were excluded; these articles did not fulfill the selection criteria because the type of surgery or IOL was not specified. Most of these studies demonstrated that cataract surgery results in significant improvements in visual function and health status, such as everyday activities and emotional health, in the first year after surgery.

For a full description of the methodology and findings of the literature review, see Appendix K in the *Guideline Report.*

The scope of the review of the literature in this guideline addresses a comparison of the two forms of extracapsular surgery, ECCE and PE. The review, however, did not deal with the details of surgical techniques, adjunctive agents used in facilitating the procedures, use of instruments for cataract removal, selection of types and styles of IOLs, techniques of IOL implantation, and the consequences of applying such materials and methods.

Benefits and Harms of Cataract Surgery

Although no data precisely define the risks and benefits of cataract surgery, some estimates can be made based on literature reports of outcome and complications.

Benefits of Cataract Surgery: Positive Outcomes. A positive outcome is the degree to which the presurgical functional impairment is relieved by the surgery, as defined by the types of benefits perceived by the patient, members of the patient's family, or the ophthalmologist who performs the surgery. Cataract surgery is a highly successful procedure. A visual result in the 20/40 to 20/15 range and an increase in well-being and quality of life can be anticipated in the vast majority of eyes without comorbidity. Generally, patients can expect an increase in well-being and quality of life 90 percent of the time. The following is a list of the types of benefits that could accrue as part of a positive outcome following cataract surgery.

- Increased ability to read or do close work.
- Increased ability to perform minimal everyday activities.
- Increased opportunity to continue or resume function or occupation (working, playing, driving) due to improvement in vision.
- Restoration of functional ability to precataract level.
- Increased mobility.
- Increased independence.
- Better uncorrected vision.
- Improved color vision.
- Reduced glare disability.
- Improved depth perception.
- Increased ability to retain a quiet eye with no treatment-induced disorders.
- Patient satisfaction with the results of surgery.
- Improved sense of mental well-being.
- Improved self-esteem.
- Relief from fear of going blind.
- Increased ability to avoid injury.
- Increased interpersonal contact.
- Increased opportunity for medical observation of the internal eye for incipient or impending diseases.

Harms of Cataract Surgery: Negative Outcomes. Harms that may occur as a result of the expected surgery may be defined as negative outcomes. These include failure to achieve the expected positive outcomes or failure to relieve or improve the preoperative functional impairment as perceived by the patient, the patient's family, or the ophthalmologist who performed the surgery. In addition, negative outcome refers to the development of complications that either impair the patient's visual function or consume resources (Table 5-3). It should be noted that these

Table 5-3. Estimated Rate of Negative Outcomes of Cataract Surgery

≥1:100	<1:100	<1:1,000	<1:10,000	<1:100,000
Glaucoma	Dislocated lens	Depression	Loss of eye	Death
Ptosis	Dilated pupils	Loss of vision	Chronic pain	Suicide
Intraocular hemorrhage	Endophthalmitis	Double vision	Psychosis	
Problems with glare	Increased need for ocular medication		Expulsive hemorrhage	
Cystoid macular edema	Retinal detachment		Systemic disease as a result of surgery	
Adverse effects from drugs used in the treatment	Bullous keratopathy			
Increased ultraviolet exposure				
Need for further surgery				

Note: Except for glaucoma, ptosis, increased ultraviolet exposure, and depression, the rate increases when there are comorbid conditions.
Source: Compiled from reviewed literature and panel consensus.

complication rates are based on data obtained from the literature review and the consensus of the panel. Therefore, they should be considered only estimates.

The success rate of cataract surgery is reduced in the presence of comorbid ocular conditions. Again, data are lacking for precise estimates of this effect, but conditions such as corneal disease leading to loss of corneal clarity, glaucoma, and retinal disorders such as retinal detachment disease, macular degeneration, and diabetic retinopathy all contribute to loss of vision and, therefore, loss of the effect of the cataract surgery. The effects may be immediate (that is, proximate to the time of the surgical effect) or may become manifest a considerable period after the surgery is complete.

Conclusions From the Literature Review

The rate of visual improvement, degree of astigmatism, and incidence of other complications in studies with large sample sizes indicate that both ECCE and PE are safe and effective procedures. The panel felt that it was logical that small-incision (i.e., less than or equal to 4 mm) cataract

surgery would cause less astigmatism than traditional cataract surgery, which is performed with a larger incision (10 mm). The panel also found some published evidence (Neumann, McCarty, Sanders et al., 1989) that is consistent with this hypothesis. However, the panel felt there were inadequate published data available as of the date of literature review to determine whether there were clinically significant differences in the amount of astigmatism that occurs in association with PE (particularly small-incision PE) vs. standard ECCE.

Conclusions of the Panel

Based on the evidence in the literature, the panel reached the following conclusions:

- Modern cataract surgery is safe and effective in restoring vision in patients with cataracts. Complication rates of modern cataract surgery are low. When complications do occur, however, they are often serious and vision threatening. It is of particular importance that the ophthalmologist who performed the surgery or is responsible for patient care during the postoperative period be prepared to diagnose and manage these conditions promptly and effectively. Effective treatment may require extensive additional complicated surgical procedures (e.g., glaucoma surgery, retinal detachment surgery, therapeutic vitrectomy, penetrating keratoplasty, or anterior segment revision). Prompt diagnosis and management of these conditions is a basic tenet of appropriate medical care.
- In the absence of comorbid conditions, a postoperative corrected visual acuity in the 20/40 to 20/15 range is a reasonable expectation for the vast majority of patients with functional impairment due to cataract. PE and ECCE surgery appear to be equally effective in restoring vision.
- The motivation for using PE in cataract surgery is enhanced safety coupled with a more rapid rehabilitation following the procedure. The rationale is that the smaller wound promotes less likelihood of wound dehiscence, more rapid healing, and reduced postoperative astigmatism. In addition, this may be advantageous in some eyes with comorbid conditions. Although these concepts are intuitively appealing, it is not possible to determine from the published literature, in a definitive manner, whether the use of the PE technique leads to a more rapid functional rehabilitation of the patient; whether the use of PE leads to less induced postoperative astigmatism; or whether specific or overall complication rates associated with PE are better, worse, or unchanged compared with the rates associated with the standard extracapsular procedure.
- Studies in the published literature demonstrate that cataract surgery results in significant improvement in visual function and overall functional status in the first postoperative year. It is not possible, however, to determine whether the use of PE over the standard

extracapsular procedure enhances the outcome when measured by reduction or elimination of functional impairment due to cataract.

Recommendations for Care

The questions raised in this portion of the literature review are central to the debate concerning technical innovations in surgery, namely the indications, contradictions, complaints, benefits, and risks of one technique as opposed to the other.

In the absence of specific guidance from the published scientific literature, the panel recommends that ophthalmologists use their best judgment in selecting the surgical techniques for individual patients with cataract. This decision regarding the appropriate technique should be made by the ophthalmologist who is to perform the surgery according to his or her training and experience and after discussion with and explanation to the patient.

It is the responsibility of the ophthalmologist who is to perform the surgery to do the following:

- Ensure that the patient has had a general medical history and physical examination as appropriate to the planned surgery and the type of anesthesia.
- Ensure that the appropriate keratometry and A-scan measurements have been performed, if an IOL is to be implanted.
- Select the appropriate IOL power after discussion with the patient, if an IOL is to be implanted.
- Review the results of presurgical and diagnostic evaluation of the patient and discuss the findings with the patient or, in appropriate cases, with another responsible adult acting for the patient.

In considering all possible benefits and harms, comorbid conditions must be taken into account. The degree to which they are treatable or being treated, or that surgery is modified to account for them, will influence the outcome. Overall, in the presence of these conditions, the success rate of the surgery is reduced from the overall high level of expected outcome in the eye without comorbid conditions. Visual loss with these comorbid conditions may occur even without surgery.

Recommendations for Research

The panel recognizes that the literature lags behind current practice in evaluating changes in clinical practice such as surgical technique. As a result, data on effectiveness and complications reported in the literature may not apply to current clinical practice.

The panel recommends that research be undertaken to develop innovative approaches for evaluating surgical outcomes so that timely data can be derived.

Second Eye Surgery

Indications for second eye surgery are the same as for first eye surgery.

Background

When an individual who has already had cataract surgery in one eye develops a vision-impairing cataract in the second eye, the patient and the ophthalmologist are confronted with the same issues regarding the decision for surgery that were present during the development of the cataract in the first eye. This section of the guideline addresses the indications for cataract surgery in the second eye and the timing of the surgical intervention.

Literature Review

Methods. The literature review process is described fully in Appendix L in the *Guideline Report.*

Results. The results of the literature review are as follows and are summarized in Evidence Table L-1 in Appendix L in the *Guideline Report.*

Question 1: Is there evidence of the indications for surgery on the second eye?

No articles were available to directly address this question. One paper (Bernth-Petersen, 1982) suggested that the need for binocularity is an indication for bilateral surgery. However, the study was performed on aphakics, no patients were pseudophakic, and followup was lost on 7 percent of the patients. There were no data on comparability of the group or reasons for bilateral vs. unilateral surgery. The second study (Maruszczak, Jensen, and Goldschmidt, 1979), performed on 100 patients below the age of 60 who were made surgically aphakic, investigated the correlation of occupational and visual needs with surgery in one or both eyes. The authors concluded that operation for unilateral cataract was inadvisable as it leads to intolerable anisometropia. Again, the study was performed only on aphakic eyes. Thirty percent of the data were missing because of loss of comparability of the group or the reasons for bilateral vs. unilateral surgery. This conclusion seems intuitively reasonable, but the fact that the study was carried out on aphakics means that this may not be directly applicable to pseudophakic patients unless there is marked refractive disparity between the two eyes.

Question 2: Is there evidence to support or refute an association between surgery on the second eye and the overall outcome? (Consider reduction of functional impairment in particular.)

No papers were found providing evidence to answer this question. However, Bernth-Petersen (1985), a review paper, analyzed a series of 12 studies that dealt with the subject of outcome. This included review of

Bernth-Petersen (1982). As a result of this review, the author felt that patients with both eyes operated on were likely to be more comfortable than patients having surgery on one eye. This is particularly true of patients who were aphakic. The author also found that the monocular pseudophakes and contact lens-corrected patients appear to be more satisfied than monocular aphakic patients or aphakic patients corrected with spectacles.

Question 3: Is there information on cost and/or cost-benefit issues?

No papers were found that directly addressed this issue.

Cost-benefit issues were only touched on in some of the papers. Nevertheless, as with the suggestions for indications and outcomes, there were a few conclusions. Restoration of binocularity, especially in working individuals, was helpful in restoring a productive person to his or her optimum status, thereby indirectly stimulating the economy and eliminating disability benefits. Also, in certain circumstances, performing surgery on both eyes in the same operating session was "economical." Once again, these data were not presented with much statistical support.

In addition, five papers (Benerza and Chirambo, 1978; Engelbrecht and Stulting, 1984; Fenton and Gardner, 1982; Henderson, 1977; Maruszczak, Jensen, Goldschmidt et al., 1979) discuss bilateral cataract surgery at the same sitting. All patients were aphakic, so the relevance to the pseudophakic patient and modern cataract surgery is questionable. These papers suffered from a variety of methodologic defects, as outlined in the evidence table. However, they do indicate the low rate of complications using this particular approach. Clayman, Jaffe, Light et al. (1977) discusses the results of cataract surgery in 730 patients, 44 of whom had bilateral implants. The authors advise a conservative approach toward surgery in the second eye in order to evaluate the success of the procedure in the first eye. This paper was written 14 years ago, when implant surgery was still being perfected, so its application to modern surgery is also questionable.

Conclusions From the Literature Review

None of the papers identified in this literature search contained information relevant to the questions posed. No precise indications for cataract surgery on the second eye were identified. The majority of these studies were on aphakic patients and, thus, were of doubtful relevance to the modern pseudophakic eye in patients. Several studies addressed outcome following bilateral surgery. Cost-benefit issues to the patient and the community were not addressed. All these papers contained a variety of methodologic defects, which considerably lessened the impact of the conclusions drawn by the authors; these are summarized in the comments of the evidence table.

The search of the literature did not reveal answers to the questions specified by the panel regarding surgery on the second eye.

Conclusions of the Panel

Although the studies concerning indications and outcomes for surgery on the second eye had significant limitations, they nevertheless provided some strong suggestions about the need for such surgery. The disabilities caused by a visual deficit in the second eye are significant (e.g., loss of binocularity and stereopsis). Since measures of visual function such as acuity, stereopsis, and visual field are all enhanced by binocular vision, the panel felt that these facts strongly support the potential benefit of surgery in the second eye. The existence of anisometropia and often aniseikonia due to disparate refractive errors, as well as the unequal visual acuity due to the presence of the cataract in the second eye, are factors that bring both patient and surgeon to the decision to operate on the second eye, even after successful visual rehabilitation of the first eye.

Costs and benefits were touched on only in some of the papers. Nevertheless, as with the suggestions for indications and outcomes, there were a few conclusions. Restoration of binocularity, especially in working individuals, was helpful in restoring productive people to their optimum status, thereby indirectly stimulating the economy and eliminating disability benefits. Also, in certain circumstances, performing surgery on both eyes in the same operating session was considered to be economically justified, although this runs the very real risk of catastrophe if there is an unrecognized problem with unsterile instruments or materials used in both eyes. Once again, these data have limited statistical support.

Recommendations for Care

In light of the lack of scientific documentation, the panel offers the following conclusions by consensus after considering the policy statement from the American Academy of Ophthalmology (1991) regarding surgery on the second eye.

When a patient with functional impairment due to bilateral cataracts has undergone surgery in one eye, surgery in the second eye is justified and appropriate when the subjective, objective, and educational criteria (outlined in the section on indications for surgery) are met. The patient and the ophthalmologist should then proceed to evaluate the need for cataract surgery in the second eye, as outlined in the section on surgical techniques and complications. As part of this evaluation, the patient should be educated about the possibility of a subsequent complication in the first eye. In the event a patient initially decides to defer surgery on the second eye, the opportunity for surgery in the future should not be denied.

There are no scientific data to indicate the optimal time interval for surgery on the second eye. The panel agrees that judgment regarding this time interval should be based on the following factors. In no case should surgery be done on both eyes at the same surgical procedure.

- The patient is able to provide informed consent for surgery on the second eye after evaluating the visual results and postoperative course of surgery on the first eye.
- Adequate time has passed to detect and treat the most immediate vision-threatening complications of cataract surgery.
- Vision in the operated eye has recovered sufficiently that the patient is not at risk of injury due to functional impairment during second eye cataract surgery and the immediate postoperative period.
- In the event that vision has not recovered or is not recoverable, there is time to arrange for adequate assistance so the patient is not at risk of injury due to functional impairment following second eye cataract surgery.

The following factors may influence the patient's and surgeon's judgment regarding the timing of surgery on the second eye:

- The distance from home of the nearest available facility for surgery and appropriate postoperative care.
- The patient has a need (e.g., occupational) for good binocular vision within a limited timeframe after the first eye surgery.
- The patient is symptomatic due to postoperative anisometropia.

Early spectacle correction or decrease in the duration of the postoperative course alone, however, is not adequate justification for performing surgery on the second eye before the patient and the ophthalmologist have had sufficient opportunity to evaluate the results from the surgery on the first eye.

An exception to these indications is the special case where the opposite eye has no useful vision. In this case, the decision for surgery is determined by the degree of vision reduction at the time the patient enters into the evaluation process. In some cases, surgery may be delayed because of the greater potential for total blindness in the event of a serious complication of surgery. It is then the obligation of the ophthalmologist to inform and educate the patient about the potential risk of total blindness. Although the decreased visual acuity and level of disability may fall well within the guidelines for cataract surgery, the worse the vision is in the fellow eye, the greater the need is for caution in considering cataract surgery in a patient's only seeing eye.

Recommendations for Research

It is clear from a review of the literature that the questions surrounding the decision to operate on the second eye have received insufficient attention in the scientific literature. The panel recommends that research be undertaken to investigate the benefits of surgery on the second eye as opposed to the benefits of surgery on one eye only, and the optimum time for that surgery to be performed when the patient has functional impairment from binocular cataracts. The cost-benefit issues related to this topic are also important and should be analyzed.

6 Guideline: Postoperative Care

From the patient's perspective, the period of postoperative care normally spans the interval from the conclusion of surgery until the goal of surgery is achieved by the provision of stable improved vision.

Background

During the past 15 years, improvements in cataract surgery have greatly changed the postoperative management of the cataract patient. The widespread use of local anesthetic instead of general anesthetic, better wound-closure techniques, and earlier visual rehabilitation with intraocular lens (IOL) implants have led to an earlier return to everyday activities.

This earlier return to everyday activities and the success of the surgery have led to a reduced need for daily face-to-face care by the surgeon. Years ago, the cataract patient would remain in the hospital for up to 7 days after surgery, and care would be personally managed daily by the surgeon. A supportive nursing staff would attend the patient throughout the hospital stay. Today, the patient may be discharged from the outpatient surgical facility within an hour of surgery. The number of postoperative visits to the surgeon and access to nursing care are often, of necessity, limited. This diminishes the collaborative care mode, thereby reducing the level of care given the patient to self-care instructions given at the time of discharge. Preparation for and supervision of the postoperative period may be inadequate to meet the needs of many patients.

From the patient's perspective, the period of postoperative care normally spans the interval from the conclusion of surgery until the goal of surgery is achieved by the provision of stable improved vision. In the absence of complications, this usually occurs by 3 months after the surgery and coincides with the prescription of a final refractive correction. It also marks the point at which wound healing has advanced sufficiently that the integrity of the eyeball has been reestablished and many of the intraoperative and postoperative complications have been diagnosed and treated. If late complications develop, they may require treatment by the ophthalmologist who performed the surgery or by another suitable, competent ophthalmologist. This treatment may then extend beyond the postoperative period. (See also Chapter 3.)

Literature Review

Methods

The purpose of the literature review was to determine if there was evidence in the published literature to support or refute an association

between the outcome of cataract surgery and the care provided in the postoperative period.

Results

The literature search identified 36 potentially relevant articles. Upon further review, 15 of these articles were found to be relevant. These 15 articles underwent indepth content and methodologic review. The results of the literature review are as follows and are summarized in Evidence Tables M-1 to M-3 in Appendix M in the *Guideline Report.*

Question 1: Is there evidence to support or refute an association between outcome and usual frequency of postoperative visits?

In the articles reviewed on the relationship of postoperative care to cataract surgery outcome, there were no studies, review articles, or case reports that critically evaluated the frequency of postoperative care in relation to outcome variables. Four clinical trials did examine the influence of various treatment regimens on intraocular pressure, or IOP (Hollands, Drance, and Schulzer, 1987; Linn, Zimmerman, Nardin et al., 1989; Ruiz, Wilson, Musgrove et al., 1987; Tomoda, Tuberville, and Wood, 1984). These articles can be used to document the incidence of acute and potentially damaging increases in IOP during the first 24 hours after surgery, since they document a high frequency of untoward increases in IOP during the first 24-hour postoperative period; e.g., 33 percent of 18 controls showed IOP greater than 25 mmHg in Ruiz, Wilson, Musgrove et al. (1987). In summary, the IOP studies provide evidence that indicates a need to provide an evaluation of IOP during the first postoperative day.

One study (Laws, Watts, Kirby et al., 1989) documented the occurrence of bacterial contaminants obtained from the lid margin and fornix during the first postoperative day and showed some positive cultures. The study was not designed to indicate whether the bacteria were pathogens, contaminants, or part of the natural flora of the patient. It cannot be used to support or refute a claim that examination is necessary on the day following surgery.

A clinical trial (Sanders and Kraff, 1984) and an observational study (Carriker, Liebowitz, Nees et al., 1987) examined the influence of various treatments on postoperative inflammation during the first 3 weeks after cataract surgery. Although the clinical trial indicated a high percentage of patients with clinically unacceptable inflammatory responses (10-47 percent in this interval), the definition of "clinically unacceptable" was subjective, making this study difficult to interpret.

Evidence for the necessity to provide more long-term followup is indicated by an observational study (Jampel, Thompson, Baker et al., 1987) of 203 consecutive patients undergoing extracapsular cataract surgery. In this study, corneal curvature was not stable until 4-6 months after surgery. Therefore, any optical correction cannot be viewed as "final"

until that approximate time period. As indicated within Evidence Table M-1 in Appendix M in the *Guideline Report*, however, the study was marred by flaws in methodology.

Three studies included in Evidence Table M-1 in Appendix M in the *Guideline Report* (Green and Peters, 1988; Kolder, 1982; Lichtenstein, 1986) provide only anecdotal information on followup schedules after cataract surgery, with no supportive evidence for the stated schedule.

In summary, there is quite convincing evidence that IOP needs to be monitored at about a 24-hour interval after surgery in order to detect patients who have potentially damaging IOP elevations. Most other complications that occur in this time period (e.g., endophthalmitis, wound dehiscence, wound leak, intraocular hemorrhage, dislocated lens) are too rare for a controlled study but can also be diagnosed. Evidence is far less abundant for postoperative evaluations at later points. Weak evidence indicates a need to evaluate the inflammatory response in operated eyes at 1-3 weeks after surgery. The refractive status of the operated eye likely does not stabilize until several months after surgery, so provision of a "final" optical correction for patients must await this time period of followup.

Question 2: Is there evidence to support or refute an association between outcome and content of visits? (Consider visual acuity, refraction, IOP measurement, slit lamp examination, dilated fundus examination, medication administration, patient education.)

In the articles reviewed on the relationship of postoperative care to cataract surgery outcome, there were no studies, review articles, or case reports that critically evaluated the content of postoperative care in relation to outcome variables. Four clinical trials did examine the influence of various treatment regimens on IOP (Hollands, Drance, and Schulzer, 1987; Linn, Zimmerman, Nardin et al., 1989; Ruiz, Wilson, Musgrove et al., 1987; Tomoda, Tuberville, and Wood, 1984). These articles document the incidence of acute and potentially damaging increases in IOP during the first 24 hours after surgery and thereby demonstrate the need to assess IOP by some method in the first postoperative day. (See Evidence Table M-2 in Appendix M in the *Guideline Report.*)

Another clinical trial (Sanders and Kraff, 1984) demonstrated the higher sensitivity of fluorophotometry for the diagnosis of postoperative inflammation over slit lamp evaluation, which was used along with ophthalmoscopy in an observational study (Carriker, Liebowitz, Nees et al., 1987) of postoperative inflammation. Keratometry was used as an objective measure of corneal curvature in an observational study of postcataract surgery eyes (Jampel, Thompson, Baker et al., 1987).

The remaining five articles in Evidence Table M-2 in Appendix M in the *Guideline Report* are reviews of potential complications of cataract surgery (Carver, 1987; Kolder, 1982; Lichtenstein, 1986; Masket, 1988;

Mizuno and Miyake, 1987). They do not present new data on these questions.

In summary, the evidence that supports essential components of a postoperative visit to a health care provider depends largely on studies that document complications of cataract surgery. Since elevated IOP, inflammation, and corneal curvature changes are known complications, the literature includes studies that utilize tonometry, fluorophotometry, and keratometry, respectively, to evaluate the postoperative eye for these possible complications. This applies as well to fundus changes, such as cystoid macular edema, which can be diagnosed by various methods of examination, including ophthalmoscopy and fluorescein angiography.

Question 3: Is there information on cost and/or cost-benefit issues?

The literature contained no specific information on cost and/or cost-benefit issues in relation to postoperative management or outcome. The most that can be gleaned from the articles listed in Evidence Table M-3 in Appendix M in the *Guideline Report* are general statements about postoperative refractive alternatives (Carver, 1987; Young and Schwab, 1989).

A number of articles provide support for practices that affect cost directly, such as use of tonometry to measure IOP or use of steroid/antibiotic drop combinations in the postoperative period, but in no case are the cost or cost-benefit implications specifically discussed. The application of health economics science, therefore, seems to be missing from the literature on postoperative management and outcome after cataract surgery.

Conclusions From the Literature Review

The literature review did not provide answers to any of the panel's questions dealing with postoperative care and outcome. However, direct evidence was provided about the importance of postoperative examination on day 1 and weaker evidence for the importance of the examination around the second or third week.

(See Appendix M in the *Guideline Report* for a full discussion of the literature review.)

Conclusions of the Panel

The literature review did not provide answers to any of the specific questions raised. However, it did provide indirect evidence of the importance of measuring IOP and assessing the degree of postoperative inflammation, likelihood of infection, integrity of the wound, and proper location of the IOL in the first 24 hours following surgery. Although the literature does not critically evaluate postoperative care in relation to outcome variables, it presumes that postoperative care will be provided by

a competent ophthalmologist who is aware of both common and rare complications of cataract surgery and is able to use the best available methods to diagnose these complications when they occur and when they are suspected. However, certain components of postoperative care can be delegated to one or more members of a team of appropriately trained professionals, including optometrists, community health nurses, and social workers.

Recommendations for Care

The panel recognizes that the literature does not provide a scientific basis for establishing guidelines for the management of cataract patients during the postoperative period. Nevertheless, some recommendations were reached by consensus. The basic structure of this agreement is the American Academy of Ophthalmology *Preferred Practice Pattern* document, "Cataract in the Otherwise Healthy Adult Eye" (1989).

Patient Education

The ophthalmologist who performs the surgery has an obligation to educate and instruct the patient regarding the following: appropriate signs or symptoms of possible complications, eye protection, activities, medications, required visits, and details for access to emergency care. The patient likewise has an obligation during the postoperative phase to follow the advice and instructions of the surgeon and to notify the surgeon promptly if problems occur.

Patient's Condition at Discharge

Patients undergoing outpatient cataract surgery will normally be discharged from the facility to their home or to another accommodation that is conveniently close so that emergency care can be provided if needed. Criteria for discharge after ambulatory surgery include:

- Stable vital signs.
- Return to preoperative mental state.
- Absence of nausea.
- Absence of significant pain.
- Availability of an escort.
- Review, with the patient or escort, of postsurgical care until the first postoperative visit on the day following surgery, including relief of pain, activity level permitted, and access to emergency care if needed.
- Prearranged followup appointment.
- Written postoperative instructions.
- Suitable environment.
- Adequate home care support.

Postoperative Hospitalization

Hospitalization after surgery may be unplanned or planned.

Operative complications of an ocular or medical nature are possible indications for unplanned postoperative hospitalization. Postoperative ocular complications can include hyphema, infection, wound dehiscence, endophthalmitis, uncontrolled elevated IOP, threatened or actual expulsive hemorrhage, retrobulbar hemorrhage, severe pain, or other ocular problems requiring immediate management or careful observation.

Medical complications can include cardiac instability, respiratory instability, a cerebrovascular episode, diabetes mellitus requiring immediate management, uncontrolled nausea or vomiting, acute urinary retention, acute psychiatric disorientation, or other medical conditions requiring immediate management or careful monitoring.

Indications for planned postoperative hospitalization are as follows:

- Medical conditions are present that require prolonged postoperative observation by a nurse or skilled personnel.
- Best correctable vision in the unoperated eye is 20/200 or worse.
- Patient is mentally debilitated, diagnosed as mentally ill, or functionally incapacitated so that a risk of injury exists in the immediate postoperative period.
- Physical disability prevents satisfactory immediate postoperative care.

Postoperative Visits

The frequency of examination during the postoperative period is predicated on the need to:

- Diagnose and provide the most efficient treatment for complications when they arise.
- Provide appropriate postoperative care as healing proceeds.
- Educate and support the patient during the postoperative period.

Fortunately, serious complications occur infrequently with modern cataract surgery (see Anesthesia, Chapter 5). However, they occur unpredictably and when untreated may have a devastating effect on the outcome of surgery. In order to minimize the risk that such complications will go unrecognized and, therefore, untreated, a schedule of visits is recommended by the panel based on the following requirements:

- The earliest practical assessment of the effects of the surgery.
- The diagnosis and treatment of immediate complications of surgery.
- The prompt diagnosis of other complications that could be potentially devastating to vision, particularly infection and glaucoma. Both of these complications may occur at any time during the postoperative period. Although the most acute bacterial infections tend to present within the first few days of surgery, less virulent but still potentially devastating

infections with other bacteria and fungi may develop in the succeeding weeks and months.

The frequency of normal followup for a patient without signs or symptoms of possible complications is:

- First visit: day after surgery.
- Second visit: approximately 1 week after surgery.
- Third visit: approximately 3 weeks after surgery.
- Fourth visit: approximately 6-8 weeks after surgery.

More frequent postoperative visits are indicated if unusual findings or complications occur.

Postoperative Examinations

The components of postoperative examinations include the following:

- Visual acuity each visit.
- IOP measurement each visit.
- External examination each visit.
- Slit lamp examination each visit.
- Patient counseling and education each visit, unless the patient's condition does not allow it. (This should include information about progress toward healing, medication instructions, level of activity permitted, symptoms requiring emergency care, and access to emergency care.)
- Ophthalmoscopy. (A dilated fundus examination to include the peripheral retina should be done at least once during this postoperative period.)

The timing and frequency of refraction will depend on patient needs, the amount of astigmatism, and the stability of the measurement. Sutures may be cut or removed by the ophthalmologist for the reduction of astigmatism. Usually, optical correction can be prescribed 6-12 weeks after surgery.

Long-Term Followup

Patients should be informed of the need for periodic eye examinations and of the possible need for YAG capsulotomy if a posterior capsular opacification develops.

Recommendations for Research

Research regarding the suitability of various practice patterns of postoperative care should be promoted. In particular, research should be directed to determine whether some of the new practice patterns encouraged by changes in legislation and reimbursement are influencing the quality of care.

7 Guideline: Rehabilitation

Numerous factors need to be considered to successfully rehabilitate the cataract patient.

Background

Outpatient cataract surgery became a reality without consideration for the rehabilitation needs of the postoperative patient. Previously, the patient enjoyed the collaborative efforts of the health care team (medical doctor, registered nurse, medical social worker, and registered dietician) preoperatively and postoperatively in the hospital setting. Upon the patient's admission for an inpatient stay, the role of the registered nurse included an assessment involving evaluation of functional limitations; exploration of potential environmental and economic concerns; and consideration of cultural, ethnic, and psychosocial factors. Compilation of these data was the basis for a discharge plan.

Postoperatively, the plan was expanded to include the appropriate education for continuation of any necessary treatments (e.g., instructions for proper instillation of eye medications and systemic medication regimen). Elimination of the traditional hospital admission procedures automatically led to discontinuance of this approach to discharge planning. Thus, planning for immediate and long-term postoperative needs became the surgeon's responsibility. Presently, the surgeon and office team are relied on to educate, instruct, evaluate, and plan for all aspects of the patient's needs in a limited preoperative time period. The immediate and brief postoperative recovery phase accompanied by the compromising effects of anesthesia may discourage fruitful educational efforts or psychosocial planning. Hence, aspects of the patient's needs may be left unaddressed. The actual effects of the current modality of cataract surgery on the rehabilitation of the patient have not been studied.

There is, therefore, valid concern about a deterioration in the quality of postoperative care as a result of ineffective discharge planning (Leader, 1990).

Literature Review

Methods

The purpose of the literature review was to determine if there was evidence in the published literature to support or refute an association between the outcome of cataract surgery and factors affecting the rehabilitation of the patient during the postoperative period. (For a full

description of the review process, see Appendix N in the *Guideline Report.*)

Results

The questions identified by the panel are as follows.

Question 1: Is there evidence to support or refute an association between outcome of cataract surgery and delivery of postoperative care at home?
Question 2: Is there evidence to support or refute an association between outcome of cataract surgery and preoperative and postoperative patient and family education and counseling?
Question 3: Is there evidence to support or refute an association between outcome of cataract surgery and functional status (physical and mental) of patients at the time of surgery?
Question 4: Is there evidence to support or refute an association between outcome of cataract surgery and financial status?
Question 5: Is there evidence to support or refute an association between outcome of cataract surgery and cultural, religious, and ethnic factors?
Question 6: Is there evidence to support or refute an association between outcome of cataract surgery and the identity of the person involved in providing postoperative rehabilitation (e.g., family member, ophthalmic nurse, registered nurse, medical social worker, or social agency)?
Question 7: Is there evidence to support or refute an association between outcome of cataract surgery and the costs and benefits of formal rehabilitation programs?

Thirty-two articles underwent indepth reviews. Although they all addressed aspects of the care of patients with cataract, none satisfied the inclusion criteria as specified by the panel.

One study (Graney, Applegate, Miller et al., 1990), which failed to meet the inclusion criteria, examined preoperative predictors of surgical success in patients with cataract and retinal disease; the authors found the availability of a helper in the home was not a prognostic indicator. The description of this portion of the study and the data were insufficient to allow an assessment of the implications of this finding.

Conclusions From the Literature Review

This literature search failed to identify evidence in the published literature to address the questions posed by the panel concerning rehabilitation of the patient undergoing cataract surgery.

Conclusions of the Panel

The implementation of outpatient cataract surgery has adversely affected the team approach to planning the individualized rehabilitative course for many patients. The collaborative efforts of professionals to customize the discharge plan within their areas of practice, followed by appropriate evaluations and modifications, have been largely abandoned. This is especially true of the role of the ophthalmic nurse and medical social worker, who have been underutilized. Appropriate planning for postoperative rehabilitation can be accomplished by office personnel interacting with the patient and family preoperatively and postoperatively or through a multidisciplinary approach using optometrists, registered nurses, community health nurses, or social workers.

In the absence of evidence in the literature on this topic, the panel agreed that the successful rehabilitation of the cataract patient involves several factors, including compliance with physician instructions, patient education, and timely management of postoperative complications. Other factors expected to influence the rehabilitation process are economic, environmental, cultural and ethnic, and psychosocial (Whitaker and Whitaker, 1991).

Compliance

Cataracts in adults tend to develop bilaterally, so poor vision in the unoperated eye may increase the degree of difficulty in instilling eyedrops. Conditions associated with the aging process, such as rheumatoid arthritis and diabetes, can result in peripheral nerve dysfunction and inhibit the medication instillation (Donnelly, 1987). Other sensory changes in old age may increase the patient's difficulty in understanding treatment and how to comply with instructions (Smith and Drance, 1984). Problems with speech discrimination and the increased time needed to process oral information may render rapid speech unintelligible.

Patient Education

Careful preoperative assessment of the abilities of the patient and family to understand and comply with instructions is critical to ensuring adequate postoperative care and is the responsibility of the surgeon and his or her staff. Education for postsurgical care most appropriately begins preoperatively. However, the focus of diagnosis, surgical procedure, and visual prognosis may provide too much information for the patient to absorb. Some patients are shocked when they learn they have cataracts, and others do not even realize the extent of the visual impairment, since the deterioration is usually a gradual process (Low, 1978). Hence, preoperative education is initiated during a difficult period and may be of limited value. The postoperative cataract patient, discharge instructions in

hand, may not be able to distinguish the normal from the abnormal response and may decline to contact the physician because of feelings of embarrassment or lack of understanding. The patient may have a written document listing the postoperative instructions but may not be able to read it because of reduced vision or other physical or mental problems (Smith and Drance, 1984). This may prevent the treatment from being accomplished successfully. Referral to a home health agency in such circumstances is appropriate for further education and evaluation of a patient's ability to follow discharge instructions.

Management of Postoperative Complications

Although serious complications after modern cataract surgery are now infrequent, their occurrence is unpredictable. Lack of provisions for immediate intervention could result in an adverse surgical outcome, particularly for the patient living alone.

Coexisting medical problems, such as arthritic deformities, insulin-dependent diabetes, hypertension, cardiac disease, drug or alcohol addiction, mental illness, dementia, severe depression, or acute grief, create a complex situation for the postoperative patient. The physical limitations from a preexisting condition may limit or prevent the patient from properly complying with the required postoperative regimen. Thus, there is the potential for ineffective treatment or overdosing of medications (Hunt, 1991). It may be difficult for patients to identify labels on eyedrops because of their altered visual status postoperatively. The use of certain ophthalmic medications by patients concurrently treated with other drug therapy heightens the potential for serious adverse systemic reactions (e.g., topical beta-blocking agents added to systemic beta blockers). In the patient with delayed recovery or unrecognized postanesthetic complications, premature discharge without appropriate planning and education could be fatal.

Economic Factors

In addition to the diagnostic and pretreatment considerations in older patients, cataract surgery may also have an adverse economic impact on patients and their families. Many patients are retired persons living on a fixed income. With the increased cost of living, some are pauperized, and others suffer significant deprivation.

Cataract surgery can present multiple problems for many patients who are ill equipped to deal with them. If they are among the "frail elderly," their needs are multiplied in the immediate postoperative period. They may need a stay in a motel for a night before surgery and a night or two after surgery. They may need assistance in the home for ambulation, transportation, meal preparation, administration of medication, and so on.

These services may be unavailable for economic reasons and may or may not be reimbursed by Medicare, depending on the circumstances.

Environmental Factors

Postoperative rehabilitation may be profoundly influenced by the patient's home environment (e.g., hazards such as broken steps, obstructed pathways, and lighting) and other factors, such as location in a high-crime area, lack of transportation, and distance from medical care support services.

Cultural and Ethnic Factors

The diverse cultural and ethnic composition of American communities can create barriers to the effectiveness of the health care provider. There is evidence that race may be a factor in determining access to health care (Sommer, Tielsch, Katz et al., 1991). Recognizing the mores and belief systems of the patient aids in developing an appropriate plan for care (Whitaker and Whitaker, 1991).

A substantial barrier to patient care is the inability to communicate with the health care provider. Failure to convey information effectively to non-English-speaking patients may adversely affect the rehabilitative outcomes. The needs of deaf patients should be accommodated to ensure that the information related is understood.

Psychosocial Factors

Learning how elderly people function in their daily lives is essential to understanding and caring for them. Their hearing and vision may be impaired, their responses may be slow, and they often have chronic physical or mental illnesses with associated discomforts and difficulties in ambulation. For several reasons, elderly people may not report their symptoms. Often, they may not want to burden their family members or friends who might be their sole mode of transportation. They may be afraid or embarrassed to do so, they may be trying to avoid medical expenses or the discomforts of diagnosis and treatment, they may think that their symptoms are merely a part of the aging process, or they may have simply forgotten about their symptoms (Bates, 1987).

A significant occurrence among the aged is the tendency toward isolation: the spouse may not be alive, the extended family may live at a distance, and/or the physical environment may not be conducive to venturing outside. The fear of losing independence may deter the patient from seeking assistance from any agency before surgery. The return home postoperatively may intensify feelings of loneliness and isolation, compounded by the anxiety of the altered visual state, delayed recovery from anesthesia, and the anticipation of compliance with postoperative

instructions. Referral for counseling should be made when indicated. Referral to local support groups—such as the National Society to Prevent Blindness, Inc. (800-331-2020)—should also be considered.

Other sensory losses cause increased difficulty in coping with the modified lifestyle. The patient with reduced vision in the unoperated eye may experience increased anxiety because of the perceived inability to dial the telephone or deal with meal preparation and other simple everyday activities. The patient may even develop psychosis due to sensory deprivation and require psychiatric consultation.

The postoperative cataract patient may have responsibilities not readily recognized by the health care team, including that of caregiver for an incapacitated spouse or child. The need to continue this status may be the principal reason for undergoing the surgery. The reality that the patient is now dependent postoperatively may create acute anxiety and an inability to cope.

Recommendations for Care

The panel makes the following recommendations for care.

- Overall supervision of planning for postoperative rehabilitation is the responsibility of the ophthalmologist who performs the surgery. Appropriate planning for postoperative care and rehabilitation can be accomplished by office personnel who interact with the patient and family preoperatively and postoperatively or through a multidisciplinary approach utilizing optometrists, registered nurses, registered visiting nurses, or social workers.
- Careful preoperative assessment of the abilities of the patient and family to understand and comply with instructions is critical to ensuring adequate postoperative care and is the responsibility of the ophthalmologist who is to perform the surgery and his or her staff. If the patient is unable to read written instructions because of reduced vision or other physical or mental problems, referral to a home health agency is appropriate for further education and evaluation of a patient's ability to follow discharge instructions.
- Based on a thorough appraisal of household support (e.g., the patient's capacity to perform certain activities, the patient's needs and plan for care, and who is available to help), Medicare and other payers should be required to make allowances for patients requiring home care during the postoperative period, including the administration of eye medications and performance of tonometry by appropriately qualified care providers.
- Instructions regarding infection control, signs and symptoms that warrant notifying the ophthalmologist, and protective and preventive measures should be reviewed with the patient both before discharge from the outpatient setting and again at home. This is to ensure accomplishment

of the postoperative regimen at home, whether independently or with the assistance of a caregiver.

- Before discharge after surgery and at postoperative visits, patients should be instructed in the safe and proper instillation of medications.
- Assessment of the aforementioned factors and their potential impact on the patient's current and future health status is best allocated to health professionals, such as nurses, who are educated as well as trained to do extensive patient interviewing and physical, psychological, and home assessments. The patient living alone may need assessment for in-home support services, such as assistance with bathing, dressing, and preparing meals.
- When cataract patients who are considering surgery have the responsibility of being the primary caretaker for another individual, they should be referred to a home health/home care agency or family service agency for help in obtaining interim assistance in fulfilling that responsibility.
- The patient's emotional and/or spiritual needs should be assessed and the appropriate pastoral support arranged. The patient's quality of life is influenced by his or her ethnic, cultural, and religious philosophy about health and illness.
- The non-English-speaking patient population requires the efforts of interpreters to ensure that the information related is understood.

Recommendations for Research

The panel makes the following recommendations for research.

- Supportive measures provided by home health nurses, visiting nurses, and social workers intuitively can be expected to have a favorable impact on the outcome. The need for and effectiveness of such measures should be studied.
- Research should be undertaken to determine if preoperative teaching, followed by a postoperative review, is sufficient patient education to eliminate noncompliance barriers to a successful postoperative rehabilitation.
- A risk assessment instrument should be developed to identify patients requiring expanded preoperative services and to evaluate the appropriateness of the home environment or the need for an alternative living arrangement postoperatively.
- Research should be funded to establish the cost-effective role of the ophthalmic registered nurse as an extension of the ophthalmologist in the community setting and home setting.
- Research should be directed toward the deficits surrounding care of the postoperative patient created by the performance of cataract surgery in the outpatient setting. The possible benefits of a team approach should be studied to develop a model for redesigning the collaborative effort that considers all aspects of patient needs.

8 Guideline: Posterior Capsular Opacification and YAG Capsulotomy

Opacification of the posterior capsule is a consequence of modern cataract surgery. As the opacification increases, the patient begins to notice a decrease in visual function that can lead to functional impairment. The approach to the management of functional impairment due to posterior capsular opacification (PCO) is similar to that of functional impairment due to cataract.

Background

PCO is a natural consequence of modern cataract surgery, whether performed by the extracapsular technique or by phacoemulsification (PE). As a result of this opacification, there is a gradual degradation in visual function that ultimately can become symptomatic to the patient. In the past, an invasive procedure involving incising the capsule with a knife (i.e., discission) was necessary to remove the opacity. This procedure was sometimes performed at the time of the cataract surgery. Now, with the availability of the YAG laser, it is possible to perform laser capsulotomy as an outpatient procedure after cataract surgery. Although YAG capsulotomy is a commonly performed procedure (over 600,000 Medicare recipients in 1991), there are few rigorously documented data available on indications for performing this procedure, the rate of immediate and long-term complications, and outcome from the perspective of the patient's quality of life after YAG capsulotomy. There is also no information on the rate of occurrence of visually significant PCO and the appropriate timing and rates of performance of the procedure.

Literature Review

Methods

The purpose of the literature review was to identify and review those articles that contained information on PCO and YAG capsulotomy in relation to functional impairment due to cataract. (For a full description of the literature review process, see Appendix O in the *Guideline Report.*)

Results

The results of the literature review are as follows and are summarized in Evidence Tables O-1 to O-5 in Appendix O in the *Guideline Report.*

The computer search identified 138 papers thought to be relevant to the topic. Three additional papers thought to be relevant to the topic were identified from a variety of sources, which brought the total article count to 141. Seventy-eight were selected for further review because the abstract of the article suggested a relevance to the subject. Of the 78 articles, 2 pairs were found to be duplicates; one of each pair was excluded, leaving a total of 76 articles. One other paper (Javitt, Tielsch, Canner et al., 1992), the product of a study by the Cataract Patient Outcomes Research Team (PORT), was accepted for review, making a total of 77 out of 142 papers. The basis for inclusion of Javitt, Tielsch, Canner et al. (1992) was the potential importance of the data despite the failure to meet inclusion criteria (i.e., unpublished manuscript). This paper was published subsequent to the review. A total of 65 articles were excluded. Of the 77 included articles, 2 pairs contained identical data (Durham and Gills [1985]/Shah, Gills, Durham et al. [1986] and Pollack, Brown, Crandall et al. [1989]/Pollack, Brown, Crandall et al. [1988]).

A review of the 77 papers showed that very few of the studies were designed to answer the questions the panel was asked to address, and most suffered from limitations common to retrospective studies or methodologic defects that severely constrained the conclusiveness of the results. These design and methodologic problems are discussed within the context of each question. In spite of these shortcomings, the reviewers felt that there was sufficient clinical information in these papers to allow for some conclusions and to provide a basis to stimulate future studies.

Since many of the studies provided information on more than one of the five questions addressed by the panel, the sum of the total number of studies for each question is greater than 77. A critical review of the available information on each question follows.

Question 1: Is there evidence on rates of occurrence of visually significant PCO?

Twelve unique articles addressed this question (Allen and Zhang, 1987; Frezzotti and Caporossi, 1990; Kooner, Dulaney, and Zimmerman, 1988; Moisseiev, Bartov, Schochat et al., 1989; Moschos, 1988; Naeser, Rask, and Hansen, 1986a [identical data reported in Naeser, Rask, and Hansen, 1986b]; Sellman and Lindstrom, 1988; Story, 1988; Straatsma, Meyer, Bastek et al., 1983; Sudhakar, Ravindran, and Natchiar, 1989; Van Oye, Budo, Galand et al., 1986; Watts, 1986). Undefined outcome, patient dropout, undefined PCO, and lack of adjustment for variation in followup time made the rate of occurrence of PCO difficult to assess. In the absence of a definition of, or a variation in the definition of, a visually significant PCO, it is likely that there is a wide variation in what is considered visually significant. Most of the studies lack a definition of this outcome. Many studies simply refer to the time of YAG capsulotomy as a surrogate for this outcome, which may be quite inaccurate. Followup time ranged from 2 weeks to 5 years, with capsular opacification rates varying from 2

to 16 percent at 1 year and up to 41 percent at 4 years. The data suggest that the incidence of visually significant PCO increases in direct proportion to postoperative followup time (Table 8-1). One paper (Frezzotti and Caporossi, 1990) suggested that patients younger than 40 years had a higher rate of visually significant PCO.

Table 8-1. PCO Incidence After Cataract Surgery

Source	Cataract Surgery	Average Followup (Months)	PCO Incidence Information
Naeser, Rask, and Hansen, 1986a	ECCE/IOL	4	3.0 percent PCO requiring YAG
Naeser, Rask, and Hansen, 1986b	--	--	12.1 percent moderate PCO without YAG
Sellman and Lindstrom, 1988	ECCE/IOL	12	7.1-16.1 percent moderate/severe Elschnig pearl migration; 2.4-4.4 percent capsular fibrosis
Watts, 1986	ECCE/IOL	17	2-4 percent capsular membrane thickening
Kooner, Dulaney, and Zimmerman, 1988	ECCE/IOL	18	15 percent posterior capsule haze
Van Oye, Budo, Galand et al., 1986	ECCE/IOL	24 (minimum)	9.8 percent requiring YAG; 20.1 percent PCO without YAG
Story, 1988	ECCE/IOL	32	4.1 percent requiring discission due to VA <20/40 or PCO-related symptoms
Moisseiev, Bartov, Schochat et al., 1989	ECCE or ECCE/IOL	48 (minimum)	41 percent PCO requiring capsulotomy
Frezzotti and Caporossi, 1990	ECCE or ECCE/IOL	60 (minimum)	7.7-14.2 percent PCO

Note: ECCE = Extracapsular cataract extraction. IOL = Intraocular lens. PCO = Posterior capsular opacification. VA = Visual acuity. YAG = Yttrium aluminum garnet.

Question 2: Is there evidence on timing and rates of performance of YAG capsulotomy?

The performance of YAG capsulotomy is an objectively identifiable endpoint, unlike the more subjective determination of the onset of visually significant PCO; however, there is wide intersurgeon variation in the criteria used to determine when this procedure is warranted. Lack of information on these criteria or use of subjective criteria (such as the surgeon's determination that the PCO was "significant") is the most critical

unknown in the 30 studies that include information on the timing and rates of performance of YAG capsulotomy (Aron-Rosa, 1985; Brown, Thomas, Belcher et al., 1985; Burratto, Ricci, and Vitali, 1985; Capone, Rehkopf, Warnicki et al., 1990; Chambless, 1985; Coonan, Fung, Webster et al., 1985; Davison, 1988; Downing, 1986; Durham and Gills, 1985 [identical data reported in Shah, Gills, Durham et al., 1986]; Flohr, Robin, and Kelley, 1985; Fourman and Apisson, 1991; Gardner, Straatsma, and Pettit, 1985; Javitt, Tielsch, Canner et al., 1992; Knolle, 1985; Koch, Liu, Gill et al., 1989; Leff, Welch, and Tasman, 1987; Lewis, Singer, Hanscom et al., 1987; Liesegang, Bourne, and Ilstrup, 1985; Maltzman, Haupt, and Cucci, 1989; Maltzman, Haupt, and Notis, 1989; Milauskas, 1987; Naeser, Rask, and Hansen, 1986a; Richter, Arzeno, Pappas et al., 1985a; Schubert, 1987; Shepherd, 1989b; Slomovic, Parrish, Forster et al., 1986; Steinert, Puliafito, Kumar et al., 1991; Stern, Taylor, and Bernstein, 1985; Van Oye, Budo, Galand et al., 1986; Wright, Wilkinson, Balyeat et al., 1988). The study by Javitt et al. (Javitt, Tielsch, Canner et al., 1992) indicates a wide range of YAG capsulotomy rates per person-year across the United States (2.5-27 percent), which is attributed to a lack of consensus on timing and indications for the procedure. There is a need to explain the twofold-to-sevenfold increase in rates of YAG capsulotomy between contiguous States such as Utah and Nevada. Perhaps because of intersurgeon variation, time-specific estimates of rates of performing YAG vary widely. Furthermore, only one study adjusted for censoring and variable followup, so most rate estimates are crude at best (Javitt, Tielsch, Canner et al., 1992) (Table 8-2).

In general, the need for YAG capsulotomy increases with increasing time after cataract surgery, with the larger studies reporting a crude incidence of 15-20 percent approximately 2 years after surgery (Table 8-3). The median and range of time from cataract surgery to YAG capsulotomy for the 22 studies that reported an average and/or range were 24 months and 1-600 months, respectively. Little information exists on the role of patient factors on the rate or timing of YAG capsulotomy.

Question 3: Is there evidence on indications, complications, and outcomes after YAG capsulotomy?

Fifty-seven studies address this question (Albert, Wade, Parrish et al., 1990; Ambler and Constable, 1988; Aron-Rosa, 1985; Axt, 1985; Bath and Fankhauser, 1986; Boen-Tan and Stilma, 1986; Brown, Stewart, Lynch et al., 1988; Brown, Thomas, Belcher et al., 1985; Burratto, Ricci, and Vitali, 1985; Canning, Capon, Sherrard et al., 1988; Capone, Rehkopf, Warnicki et al., 1990; Chambless, 1985; Channell and Bechman, 1984; Clorfeine and Parker, 1984; Corboy and Novak, 1989; Dardenne, Gerten, Kokkas et al., 1989; Deutsch and Goldberg, 1985; Durham and Gills, 1985 [identical data reported in Shah, Gills, Durham et al., 1986]; Ficker and Steele, 1985; Flohr, Robin, and Kelley, 1985; Fourman and Apisson, 1991; Gardner, Straatsma, and Pettit, 1985; Harris, Herman, and Fagadau, 1985; Javitt,

Table 8-2. Incidence of YAG Capsulotomy After Cataract Extraction

Source	Cataract Surgery	Average Followup (Months)	YAG Incidence Information (Percent)
Naeser, Rask, and Hansen, 1986a[1]	ECCE/IOL (N=66 eyes)	Mean=4	3
Milauskas, 1987	ECCE/IOL (N=732 eyes)	Mean=9	7.0-27.9
Van Oye, Budo, Galand et al., 1986	ECCE/IOL (N=214 eyes)	24 (minimum)	9.8
Downing, 1986	ECCE/IOL (N=757 eyes)	12-62	11.2
Maltzman, Haupt, and Cucci, 1989	ECCE/IOL (N=187 eyes)	Mean=24	15.1-20.8
Davison, 1988	ECCE (N=3,120 eyes)	At least 12	16.1
Shepherd, 1989b	ECCE/IOL (N=228 eyes)	12 (all eyes)	4.8-16.5
Coonan, Fung, Webster et al., 1985	ECCE (N=842 eyes)	Mean=32 (at least 12)	16.7
Javitt, Tielsch, Canner et al., 1992	ECCE (N=55,103 eyes)	Mean=24 (range, 12-36)	24
Wright, Wilkinson, Balyeat et al., 1988	ECCE/IOL (N=50 eyes)	6 (all eyes)	38
Fourman and Apisson, 1991	ECCE/IOL (N=732 eyes)	Not reported	53

[1]Identical data reported in Naeser, Rask, and Hansen, 1986b.
Note: ECCE = Extracapsular cataract extraction. IOL = Intraocular lens. YAG = Yttrium aluminum garnet.

Tielsch, Canner et al., 1992; Katzen, Fleischman, and Trokel, 1983; Knighton, Slomovic, and Parrish, 1985; Knolle, 1985; Koch, Liu, Gill et al., 1989; Kraff, Sanders, and Lieberman, 1985; Leff, Welch, and Tasman, 1987; Levy and Dodick, 1984; Levy and Pisacano, 1985; Lewis, Singer, Hanscom et al., 1987; Leys, Pameijer, and de Jong, 1985; Liesegang, Bourne, and Ilstrup, 1985; MacEwen and Baines, 1989; Maltzman, Haupt, and Cucci, 1989; Maltzman, Haupt, and Notis, 1989; Migliori, Beckman, and Channell, 1987; Milauskas, 1987; Nirankari and Richards, 1985; Ober, Wilkinson, Fiore et al., 1986; Peyman, Caldwell, Conway et al., 1985; Pollack, Brown, Crandall et al., 1989 [identical data reported in Pollack, Brown, Crandall et al., 1988]; Richter, Arzeno, Pappas et al., 1985a and 1985b; Rickman-Barger, Florine, Larson et al., 1989; Schubert, 1987;

Table 8-3. Timing of YAG Capsulotomy After Cataract Extraction (Months)

Source	Average Interval	Standard Deviation	Range
Coonan, Fung, Webster et al., 1985	24	NR	2-88
Ambler and Constable, 1988	24	NR	4-47
Chambless, 1985	NR	NR	1.5-114
Stern, Taylor, and Bernstein, 1985	24	NR	2-69
Knolle, 1985	25-36	NR	<3->72
Flohr, Robin, and Kelley, 1985	26	17	3-106
Slomovic, Parrish, Forster et al., 1986	24	NR	2-360
Durham and Gills, 1985[1]	24	NR	2->72
Aron-Rosa, 1985	NR	NR	7-420
Koch, Liu, Gill et al., 1989	27	NR	3-124
Gardner, Straatsma, and Pettit, 1985	13	NR	1-600
Brown, Thomas, Belcher et al., 1985	15	NR	3-36
Leff, Welch, and Tasman, 1987	15	NR	2-68
Capone, Rehkopf, Warnicki et al., 1990	23	NR	8-38
Javitt, Tielsch, Canner et al., 1992	12	08	0-24
Fourman and Apisson, 1991	17	12	NR
Liesegang, Bourne, and Ilstrup, 1985	34	NR	NR
Burratto, Ricci, and Vitali, 1985	17	NR	NR
Maltzman, Haupt, and Notis, 1989	24	NR	NR
Schubert, 1987	23	03	NR
Richter, Arzeno, Pappas et al., 1985a	12	03	NR
Lewis, Singer, Hanscom et al., 1987	13	NR	4-54

[1]Identical data reported in Shah, Gills, Durham et al., 1986.
Note: NR = Not reported.

Shepherd, 1989b; Silverstone, Novack, Kelley et al., 1988; Slomovic and Parrish, 1985; Slomovic, Parrish, Forster et al., 1986; Stark, Worthen, Holladay et al., 1985; Steinert, Puliafito, Kumar et al., 1991; Stern, Taylor, and Bernstein, 1985; Stilma and Boen-Tan, 1986; Wasserman, Axt, and Sheets, 1985).

Most of the articles that included information on the indication for YAG capsulotomy made reference to some form of interference with the patient's ability to see well. In the two articles wherein this interference was quantified, the most prevalent measure used was best corrected visual

acuity of 20/50 or worse in the presence of "significant" PCO (Maltzman, Haupt, and Cucci, 1989; Stern, Taylor, and Bernstein, 1985), whereas glare, light sensitivity, and/or hazy vision without decreased visual acuity were mentioned but not quantified in five papers (Chambless, 1985; Maltzman, Haupt, and Cucci, 1989; Maltzman, Haupt, and Notis, 1989; Milauskas, 1987; Shepherd, 1989b). Most articles either did not indicate the reason for YAG capsulotomy (n=13) or indicated that the reason for YAG capsulotomy was an opacified posterior capsule (n=6) or a clinical judgment (n=4).

Complications and outcomes of YAG capsulotomy were addressed in all of the 57 articles. Whereas the information on intraoperative and early postoperative complications is good in quality and comprehensive in scope, limited information exists on long-term complications. That which exists suffers from incomplete followup and uncertainties about the content and frequency of followup examinations. In addition, the literature showed that patient characteristics affect the incidence of complications. The rate of occurrence of complications following YAG capsulotomy is shown in Table 8-4.

Table 8-4. Complications of YAG Capsulotomy

Complication	Rate of Occurrence (Percent)	
	Lowest	Highest
Increased glare	Rare	Rare
Retinal detachment	0	4.1
Cystoid macular edema	0	6.8
Endothelial cell loss	0	7
Uveitis	<0.1	30
Corneal edema	1	2.4
Hyphema	1	9
Intraocular pressure elevation	2	95
Intraocular lens damage	4.4	95
Anterior vitreous rupture	6	41

Note: YAG = Yttrium aluminum garnet.
Source: Compiled from 57 reviewed articles and panel consensus.

The literature on outcomes and complications is discussed according to those articles that addressed elevated intraocular pressure (IOP) and retinal detachment and those that evaluated other outcomes and/or complications.

Elevated IOP: The most frequently studied complication of YAG capsulotomy is elevated IOP, with 37 articles included in this review (Aron-Rosa, 1985; Axt, 1985; Bath and Fankhauser, 1986; Boen-Tan and

Stilma, 1986; Brown, Stewart, Lynch et al., 1988; Brown, Thomas, Belcher et al., 1985; Burratto, Ricci, and Vitali, 1985; Canning, Capon, Sherrard et al., 1988; Chambless, 1985; Channell and Bechman, 1984; Deutsch and Goldberg, 1985; Durham and Gills, 1985 [identical data reported in Shah, Gills, Durham et al., 1986]; Ficker and Steele, 1985; Flohr, Robin, and Kelley, 1985; Fourman and Apisson, 1991; Gardner, Straatsma, and Pettit, 1985; Harris, Herman, and Fagadau, 1985; Knolle, 1985; Kraff, Sanders, and Lieberman, 1985; Levy and Dodick, 1984; Levy and Pisacano, 1985; Leys, Pameijer, and de Jong, 1985; Liesegang, Bourne, and Ilstrup, 1985; Migliori, Beckman, and Channell, 1987; Nirankari and Richards, 1985; Peyman, Caldwell, Conway et al., 1985; Pollack, Brown, Crandall et al., 1989 [identical data reported in Pollack, Brown, Crandall et al., 1988]; Richter, Arzeno, Pappas et al., 1985a and 1985b; Schubert, 1987; Silverstone, Novack, Kelley et al., 1988; Slomovic and Parrish, 1985; Stark, Worthen, Holladay et al., 1985; Steinert, Puliafito, Kumar et al., 1991; Stern, Taylor, and Bernstein, 1985; Stilma and Boen-Tan, 1986; Wasserman, Axt, and Sheets, 1985).

Since definitions vary widely on what is considered "elevated IOP" and since even in the early postoperative period the timing of IOP measurement varied considerably, the IOP data are difficult to evaluate. The studies indicate that IOP may be elevated significantly during the first 24-48 hours after YAG capsulotomy. A report on one series of 66 patients (Slomovic and Parrish, 1985) that defined increased IOP as at least 5 mmHg over pre-YAG IOP showed a frequency of 53 percent at 1 hour, 65 percent at 2 hours, 61 percent at 3 hours, 55 percent at 4 hours, and 20 percent at 24 hours. The degree to which these elevations persist in patients is a topic of current study, and a recent article (Steinert, Puliafito, Kumar et al., 1991) reported an incidence of 1.3 percent new glaucoma or worsened preexisting glaucoma in 897 eyes that had undergone YAG capsulotomy. Most articles, however, report that early postoperative IOP elevations were responsive to treatment. Late onset (occurring 6 months or more after YAG capsulotomy) of elevated IOP was noted in 5.9 percent of 237 eyes that had undergone extracapsular cataract extraction (ECCE) with later YAG capsulotomy (Fourman and Apisson, 1991).

Retinal Detachment: Information on retinal detachment after YAG capsulotomy was reported in 16 articles (Ambler and Constable, 1988; Axt, 1985; Bath and Fankhauser, 1986; Chambless, 1985; Dardenne, Gerten, Kokkas et al., 1989; Durham and Gills, 1985; Harris, Herman, and Fagadau, 1985; Javitt, Tielsch, Canner et al., 1992; Knolle, 1985; Koch, Liu, Gill et al., 1989; Leff, Welch, and Tasman, 1987; MacEwen and Baines, 1989; Ober, Wilkinson, Fiore et al., 1986; Rickman-Barger, Florine, Larson et al., 1989; Stark, Worthen, Holladay et al., 1985; Steinert, Puliafito, Kumar et al., 1991). Except for the study by Javitt et al. (Javitt, Tielsch, Canner et al., 1992), no articles accounted for variable followup and censoring in the analysis, resulting in incidence estimates that are crude at best. Those studies that followed series of YAG patients

reported a crude retinal detachment incidence ranging from 0 to 4.1 percent, whereas the 36-month post-ECCE probability of retinal detachment in patients who required YAG capsulotomy was 1.8 percent (Javitt, Tielsch, Canner et al., 1992). For this occurrence, five articles (Dardenne, Gerten, Kokkas et al., 1989; Javitt, Tielsch, Canner et al., 1992; Leff, Welch, and Tasman, 1987; MacEwen and Baines, 1989; Rickman-Barger, Florine, Larson et al., 1989) evaluated risk factors, including high myopia, younger age, male sex, lattice degeneration, and a history of retinal detachment in the fellow eye. However, estimates of relative risk are available only in the study by Javitt et al. (Javitt, Tielsch, Canner et al., 1992), which could not address clinical variables not present in the Medicare data base. In that study, patients who underwent YAG capsulotomy had a 3.9-fold increase in retinal detachment risk when compared with ECCE patients who did not undergo this procedure. This risk was independent of other significant factors that increased the post-ECCE risk of retinal detachment, including younger age, male sex, and white race.

Other Outcomes and/or Complications: Other outcomes and complications included improved visual acuity, opening of the posterior capsule, improved glare threshold, uveitis, intraocular lens (IOL) damage, cystoid macular edema, vitreous prolapse, endothelial cell loss, hyphema, and pupillary block. Visual acuity improvement was noted in 22 articles (Albert, Wade, Parrish et al., 1990; Axt, 1985; Bath and Fankhauser, 1986; Burratto, Ricci, and Vitali, 1985; Capone, Rehkopf, Warnicki et al., 1990; Chambless, 1985; Deutsch and Goldberg, 1985; Durham and Gills, 1985; Flohr, Robin, and Kelley, 1985; Gardner, Straatsma, and Pettit, 1985; Harris, Herman, and Fagadau, 1985; Katzen, Fleischman, and Trokel, 1983; Knighton, Slomovic, and Parrish, 1985; Knolle, 1985; Levy and Dodick, 1984; Levy and Pisacano, 1985; Nirankari and Richards, 1985; Peyman, Caldwell, Conway et al., 1985; Stark, Worthen, Holladay et al., 1985; Steinert, Puliafito, Kumar et al., 1991; Stern, Taylor, and Bernstein, 1985; Wasserman, Axt, and Sheets, 1985), and improvement was observed in 65-100 percent of those undergoing YAG capsulotomy. However, variation in followup after YAG capsulotomy was considerable, and losses to followup were often substantial. Reporting of both pre- and post-YAG visual acuity was often lacking, and when present, often categorical rather than patient specific. Capsular opening was specified in four papers and ranged from 97 to 100 percent (Capone, Rehkopf, Warnicki et al., 1990; Gardner, Straatsma, and Pettit, 1985; Lewis, Singer, Hanscom et al., 1987; Stark, Worthen, Holladay et al., 1985). An increase in the glare threshold after YAG capsulotomy was noted in two articles (Capone, Rehkopf, Warnicki et al., 1990; Knighton, Slomovic, and Parrish, 1985).

Other than IOP elevation, the most commonly reported complication was damage to the patient's IOL, which was reported in 20 unique articles with a frequency ranging from 4.4 to 95 percent (Aron-Rosa, 1985; Axt, 1985; Bath and Fankhauser, 1986; Burratto, Ricci, and Vitali, 1985;

Chambless, 1985; Corboy and Novak, 1989; Deutsch and Goldberg, 1985; Durham and Gills, 1985 [identical data reported in Shah, Gills, Durham et al., 1986]; Flohr, Robin, and Kelley, 1985; Gardner, Straatsma, and Pettit, 1985; Harris, Herman, and Fagadau, 1985; Levy and Dodick, 1984; Levy and Pisacano, 1985; Lewis, Singer, Hanscom et al., 1987; Liesegang, Bourne, and Ilstrup, 1985; Nirnakari and Richards, 1985; Peyman, Caldwell, Conway et al., 1985; Stark, Worthen, Holladay et al., 1985; Stern, Taylor, and Bernstein, 1985; Wasserman, Axt, and Sheets, 1985). The damage usually took the form of minor surface pitting. Two articles (Gardner, Straatsma, and Pettit, 1985; Nirankari and Richards, 1985) reported lost vision in two patients due to the IOL damage. Rupture of the anterior vitreous face was noted in eight papers (Bath and Fankhauser, 1986; Ficker and Steele, 1985; Harris, Herman, and Fagadau, 1985; Koch, Liu, Gill et al., 1989; Lewis, Singer, Hanscom et al., 1987; Nirankari and Richards, 1985; Schubert, 1987; Stark, Worthen, Holladay et al., 1985), with a frequency ranging from 6 to 41 percent of eyes.

Ten unique articles (Albert, Wade, Parrish et al., 1990; Axt, 1985; Bath and Fankhauser, 1986; Chambless, 1985; Durham and Gills, 1985 [identical data reported in Shah, Gills, Durham et al., 1986]; Harris, Herman, and Fagadau, 1985; Knolle, 1985; Levy and Pisacano, 1985; Lewis, Singer, Hanscom et al., 1987; Steinert, Puliafito, Kumar et al., 1991) evaluated the post-YAG frequency of cystoid macular edema, but because of the unavailability of pre-YAG angiographic documentation in all but one article (Albert, Wade, Parrish et al., 1990), the postoperative rates of cystoid macular edema (which ranged from 0 to 6.8 percent) cannot be interpreted as incidence estimates.

Eleven articles (Axt, 1985; Burratto, Ricci, and Vitali, 1985; Chambless, 1985; Gardner, Straatsma, and Pettit, 1985; Harris, Herman, and Fagadau, 1985; Levy and Dodick, 1984; Levy and Pisacano, 1985; Lewis, Singer, Hanscom et al., 1987; Peyman, Caldwell, Conway et al., 1985; Stark, Worthen, Holladay et al., 1985; Wasserman, Axt, and Sheets, 1985) reported on post-YAG uveitis, which was usually mild and was found in 1-30 percent of examined eyes at variable post-YAG time periods. The definition of uveitis was not standardized. Corneal endothelial cell loss was reported in five articles (Axt, 1985; Kraff, Sanders, and Lieberman, 1985; Liesegang, Bourne, and Ilstrup, 1985; Slomovic, Parrish, Forster et al., 1986; Wasserman, Axt, and Sheets, 1985) and ranged from 0 to 7 percent. Mild transitory corneal edema ranging from 1 to 2.4 percent was reported in three articles (Levy and Dodick, 1984; Levy and Pisacano, 1985; Liesegang, Bourne, and Ilstrup, 1985), and iris bleeding with hyphema ranging from 1 to 2.4 percent was noted in seven papers (Bath and Fankhauser, 1986; Deutsch and Goldberg, 1985; Flohr, Robin, and Kelley, 1985; Gardner, Straatsma, and Pettit, 1985; Harris, Herman, and Fagadau, 1985; Levy and Pisacano, 1985; Nirankari and Richards, 1985). The association of preoperative ocular, systemic, or demographic factors

with the risk of YAG-related complications received little attention in this literature.

The quality of information in the large number of articles that describe intraoperative and early postoperative complications and visual acuity results is quite good (see Table 8-4). However, the manner in which data are presented on the IOP rise during the first 24-48 hours varies somewhat. The accuracy and comparability of estimated rates of longer term complications and outcomes are affected by incomplete followup and uncertainties regarding the frequency and content of followup examinations. Only one (Javitt, Tielsch, Canner et al., 1992) of the studies of retinal detachment after YAG capsulotomy adjusted for variable followup, so the estimates are affected by this factor. Definitions of some outcomes (e.g., uveitis) are not standardized, and postoperative incidence estimates of cystoid macular edema are suspect in those studies that lack complete pre-YAG angiography. Patient characteristics may affect the incidence of complications.

Question 4: Is there evidence on rates of occurrence of PCO in relation to IOL design?

Of the 10 unique articles (Downing, 1986; Liesegang, Bourne, and Ilstrup, 1985; Maltzman, Haupt, and Cucci, 1989; Milauskas, 1987; Naeser, Rask, and Hansen, 1986a [identical data reported in Naeser, Rask, and Hansen, 1986b]; Sellman and Lindstrom, 1988; Shepherd, 1989b; Story, 1988; Van Oye, Budo, Galand et al., 1986; Watts, 1986) that evaluated the role of IOL design in opacification of the posterior capsule, all but one were retrospective in design and employed subjective criteria for defining either opacification or the need for YAG capsulotomy. Outcome assessment was not masked with regard to IOL design in any study, and followup varied in duration and completeness. The comparability of patients receiving the alternative IOL designs was provided for in only the single clinical trial (Sellman and Lindstrom, 1988). Three studies (Downing, 1986; Liesegang, Bourne, and Ilstrup, 1985; Sellman and Lindstrom, 1988) compared lens designs that provided contact with the posterior capsule with a design that did not, and a fourth study (Shepherd, 1989b) compared sulcus-fixed with bag-fixed lenses. All four reported higher rates of opacification or YAG capsulotomy with the lenses that were not in contact with the posterior capsule. Because of serious methodologic deficiencies in these studies, any conclusions must await confirmation by further, well-designed studies.

Methodologic deficiencies in the studies that attempted to address this question precluded any conclusions regarding the relationship of PCO to IOL design.

Question 5: Is there information on cost and/or cost-benefit issues?

Only one article (Rich, 1987) was identified on this topic, comparing direct costs of inpatient surgery for posterior capsulotomy using non-YAG procedures with outpatient surgery using a YAG laser. No attempt was

made to estimate indirect costs associated with either approach, and direct-cost capture was incomplete and crude at best. Benefits are not addressed in economic terms.

Conclusions of the Panel

In light of the evidence from the literature review, the panel reached the following conclusions by consensus.

- Opacification of the posterior capsule is a consequence of modern cataract surgery. As the opacification increases, the patient begins to notice a decrease in visual function that can lead to functional impairment.
- The time of onset of capsular opacification after cataract surgery is quite variable, as is the frequency with which YAG capsulotomy is performed.
- The diagnosis of functional impairment due to capsular opacification is made based on clinical judgment regarding visual loss and/or symptoms of glare and symptoms of decreased contrast in combination with the appearance of the posterior capsule.
- Capsular opacification severe enough to impair function significantly and thus require YAG capsulotomy should be a rare occurrence within 3 months of modern cataract surgery and uncommon in the first 6 months. Based on data in the literature, the rate in the first 2 years after surgery appears to be less than 25 percent. However, the panel has no basis for determining whether this is the optimum rate for YAG capsulotomy over this period.
- YAG capsulotomy is an effective procedure when used appropriately. However, it is subject to complications, some of which, though not common, are potentially blinding.

Recommendations for Care

The panel agreed unanimously that laser capsulotomy is a surgical procedure because:

- Its performance requires preoperative evaluation and diagnosis and formal patient education and consent.
- It involves destruction or cutting of ocular tissue.
- It alters tissue relationships within the eye.
- It is subject to immediate and long-term complications that require diagnosis and management and that are potentially threatening to vision.

The panel concurred that the approach to the management of functional impairment due to PCO is similar to that of functional impairment due to cataract and that management should be considered under the following headings:

- Diagnosis.
- Indications for surgery.

- Contraindications.
- Preoperative evaluations.
- Surgical technique and complications.
- Postoperative care and long-term followup.
- Benefits and harms.

Diagnosis

The diagnosis of functional impairment due to PCO is made in the context of a patient who had previously undergone cataract surgery and who now has an opacified posterior capsule. The same general approach as that outlined for cataract should be followed. However, the patients who have PCO differ from those with cataract in an important way. Generally, PCO develops more rapidly than cataract. Thus, the patient with PCO has enjoyed improved vision in the more recent past. Therefore, in this context, diagnosis involves a consideration of the following:

- The degree of functional impairment.
- The amount of PCO.
- Other possible causes of decreased vision following cataract surgery.

The panel concurred with the finding of the literature review that there is yet no objective method of relating the degree of capsular opacification to the severity of functional impairment.

Indications for Surgery

Laser capsulotomy is appropriate and justified when the following subjective, objective, and educational criteria are met, as outlined in Indications for Surgery in Chapter 5.

- *Subjective:* The ability to carry out needed or desired activities is impaired.
- *Objective:* The eye examination confirms the diagnosis of PCO and excludes other ocular causes of functional impairment.
- *Educational:* The patient has been educated about the risks and benefits of laser surgery to the posterior capsule.

The patient determines if the expected improvements in the disability outweigh the risks and costs of laser surgery.

Occasionally, laser capsulotomy is indicated for reasons other than improving functional disability—to provide a better visualization of the posterior pole to diagnose and treat retinal detachment, macular disease, and diabetic retinopathy; to evaluate the optic nerve head; and to diagnose posterior pole tumors or other conditions requiring ophthalmologic evaluation.

Contraindications

The panel concurred that there are no absolute contraindications to the performance of YAG capsulotomy in an appropriately diagnosed and informed patient, i.e., a patient who has undergone uncomplicated modern cataract surgery—extracapsular technique or phacoemulsification (PE). However, incisional capsulotomy may be indicated in those patients who cannot comply with the requirements for YAG capsulotomy by reason of physical or mental impairment or whose membrane thickness precludes successful laser surgery. YAG capsulotomy should not be performed prophylactically or scheduled routinely at particular times after cataract surgery. For reasons of improving functional impairment, it should seldom be necessary in the first 3 months after surgery and should be infrequently required prior to 6 months. Based on data in the published literature (see Table 8-3), the rate in the first 2 years is less than 25 percent. However, the panel has no basis for determining whether this is the best possible rate. The time at which PCO may require laser surgery cannot be predicted, and it is seldom indicated before 3 months after surgery. Additionally, laser surgery carries its own risks. Therefore, laser capsulotomy should never be scheduled at the time cataract surgery is scheduled or performed. Justification for performing the procedure should be well documented in the patient's record. This is particularly important in light of the recent evidence of an overall increased risk of retinal detachment following YAG capsulotomy (Javitt, Tielsch, Canner et al., 1992).

Preoperative Ophthalmic Evaluation

The panel did not evaluate the use of tests of contrast sensitivity, glare, and potential vision in the management of PCO. Fluorescein angiography may be indicated when there is clinical evidence of macular disease and/or the degree of capsular opacity appears insufficient to account for the level of decreased visual acuity. This should be documented in the chart. B-scan ultrasonography is indicated when the degree of capsular opacification is of a severity that the posterior pole cannot be visualized and when the degree of central visual loss is severe and seemingly unexplained by the degree of opacification. The preoperative ophthalmic evaluation should include a history and complete ocular examination.

Preoperative Medical Evaluation

YAG capsulotomy is a surgical procedure that is performed without the need for regional anesthesia other than an application of topical anesthetic to the cornea. However, vasoactive drugs (e.g., aproclonidine and beta-adrenergic blocking agents) are commonly used in the perioperative period. The panel concurs that it is the responsibility of the

ophthalmologist who will perform the laser surgery to assess the medical suitability of the patient for the procedure and the use of these agents in the perioperative phase.

Surgical Technique

Laser surgery of the posterior capsule is performed in the office, ambulatory surgical center, or a hospital outpatient department, under biomicroscopic magnification. A contact lens may be used to enhance visualization of the posterior capsule and help stabilize the eye during the procedure. The literature search did not address technical aspects of the surgical procedure. However, the panel concurred that careful consideration should be given to the amount of energy used, the size of the opening, and its location, since these may influence the subsequent risk of complications.

Complications

The major complications of YAG laser capsulotomy include elevated IOP, retinal detachment, cystoid macular edema, damage to the IOL, hyphema, dislocation of the IOL, and corneal edema.

Postoperative Care

The ophthalmologist who performed the laser capsulotomy has an ethical and legal responsibility to provide postoperative care to the patient. The postoperative period is considered to extend 2 weeks from the end of the procedure. If complications develop (e.g., persistent elevated IOP, retinal detachment, cystoid macular edema, or corneal abrasion), the ophthalmologist has the obligation to provide appropriate care or, with the patient's consent, to refer to another ophthalmologist.

Postoperative Care (Immediate). Patients who have undergone laser capsulotomy must be observed for at least 1 hour for evidence of elevated IOP. If the pressure is elevated, appropriate treatment must be instituted and the patient followed until the problem is resolved.

Postoperative Care (1-2 Weeks). Within 2 weeks of the procedure, the patient should be reexamined by the ophthalmologist who performed the laser capsulotomy, and the eye should be refracted as necessary. The examination should also include measurement of IOP, slit lamp examination of the anterior segment to confirm the adequacy of laser capsulotomy and stability of the IOL, and indirect ophthalmoscopy for retinal tears or detachment. In light of the increased risk of retinal detachment after YAG capsulotomy, patients should be instructed about symptoms of retinal detachment and the need for immediate examination if they develop. Patients should also be instructed about the slight long-term

risks of glaucoma and complications and about the need for periodic eye examinations.

Benefits and Harms of YAG Capsulotomy

As in the case of cataract surgery, there are no data that precisely define the risk and benefits of YAG capsulotomy. However, some estimates can be made based on literature reports of outcomes and complications.

Benefits: Positive Outcomes. YAG capsulotomy is a highly successful procedure. In eyes without comorbidity, a visual improvement can be expected in greater than 65 percent of the cases. The same positive outcomes as outlined in the section on positive outcomes for cataract surgery apply to YAG capsulotomy (see Surgical Techniques and Complications in Chapter 5).

Harms: Negative Outcomes. Harms that may occur as a result of YAG capsulotomy may be defined as negative outcomes. These include failure to achieve expected positive outcomes or failure to relieve or improve the preoperative functional impairment as perceived by the patient, the patient's family, or the ophthalmologist who performed the YAG capsulotomy. In addition, negative outcomes refer to the development of complications that either impair the patients' visual function or consume their resources (Table 8-5). It should be noted that these complication rates are based on data obtained from the literature review and the consensus of the panel. Therefore, they should be considered only estimates.

Table 8-5. Estimated Rate of Negative Outcomes of YAG Capsulotomy

≥1:100	<1:100	<1:10,000	<1:100,000
Glaucoma	Retinal detachment	Double vision	Loss of eye
Failure to improve	Problems with glare	Dislocated lens	Chronic pain
Increased need for medication	Cystoid macular edema	Disorientation	Depression
Adverse effects from the drugs used in treatment	Need for further surgery	Clinically significant damage to intraocular lens	Psychosis
	Loss of permanent vision		Suicide

Note: Except for failure to improve, disorientation, and clinically significant damage to intraocular lens, the rate increases when there are comorbid conditions. The rate <1:1,000 is not applicable to this table. YAG = Yttrium aluminum garnet.
Source: Compiled from reviewed literature and panel consensus.

The success rate of YAG capsulotomy is reduced in the presence of comorbid ocular conditions. Again, data are lacking to give precise estimates of this effect, but outcome is influenced by conditions such as corneal disease leading to loss of corneal clarity, preexisting glaucoma, and preexisting retinal disorders such as retinal detachment disease, macular degeneration, and diabetic retinopathy. Each contributes to a loss of vision and, therefore, to a loss of the effect of the YAG capsulotomy. This may be immediate (that is, proximal to the time of surgical effect) or may be manifested a considerable time after the YAG capsulotomy is complete.

In considering all possible benefits and harms, these conditions must be taken into account. The degree to which they are treated or will be treated will influence the outcome. Overall, in the presence of these conditions, the success rate of the YAG capsulotomy is reduced compared with the overall high level of the expected outcome in the eye without these comorbid conditions.

Recommendations for Research

The findings from the literature review indicate that there are wide variations in rates and timing of YAG capsulotomy after cataract surgery. This suggests the possibility of inappropriate use of this procedure. Therefore, the panel recommends that research be undertaken to evaluate the factors that influence the decision to proceed with YAG capsulotomy, including the physician, the patient, and the eye-related factors, with special emphasis on variation in physician procedure patterns related to geographic location.

The panel recommends that research be undertaken to identify risk factors for PCO and to develop measures that reduce or eliminate PCO.

The panel also recommends that research be undertaken to establish the relationship of specific aspects of the surgical technique of laser capsulotomy to the risk of complications.

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Acronyms

ARMD	Atrophic retinal macular degeneration
BAT	Brightness acuity tester
BFE	Blue field entoptoscope
BUN	Blood-urea-nitrogen
CF	Count fingers
CI	Clinical index
CNS	Central nervous system
CS	Contrast sensitivity
CSF	Contrast sensitivity function
ECCE	Extracapsular cataract extraction
ERG	Electroretinogram
GD_{CS}	Glare disability as measured by reduction in contrast sensitivity
GD_{VA}	Glare disability as measured by reduction in visual acuity
HM	Hand motion
ICCE	Intracapsular cataract extraction
IOL	Intraocular lens
IOP	Intraocular pressure
LP	Light perception
MD	Macular degeneration
Nd:YAG	Neodymium:yttrium aluminum garnet
NHANES	National Health and Nutrition Examination Survey
PAM	Potential acuity meter
PCO	Posterior capsular opacification
PE	Phacoemulsification
PORT	Patient Outcomes Research Team
PSC	Posterior subcapsular
Se	Sensitivity
SMD	Senile macular degeneration
Sp	Specificity
TVA	True Vision Analyzer
UV-B	Ultraviolet-B
VA	Visual acuity
VEP	Visually evoked potentials
VER	Visually evoked responses
YAG	Yttrium aluminum garnet

Glossary

Cataract: An opacity of the crystalline lens of the eye; a loss of transparency of the lens of the eye or of its capsule.

Cataract surgery: Removal of an opacified lens (cataract) from the eye to restore sight. See extracapsular cataract extraction surgery, intracapsular cataract surgery, phacoemulsification cataract surgery.

Complications: Ailments secondary to the original complaint or the treatment; diseases or other disorders that arise in a patient from a preexisting disorder or from an unrelated cause within the same patient. Complications may result from treatment, e.g., postsurgical infection in a patient.

Contrast sensitivity tests: Tests designed to measure the amount of contrast required to detect a specific stimulus. Contrast sensitivity testing attempts to determine the eye's ability to detect subtle variations of shading by presenting letters, figures, or sine wave gratings that are varied in contrast, luminance, and spatial frequency.

Cornea: The transparent structure forming the anterior part of the fibrous tunic of the eye. It consists of five layers: the anterior corneal epithelium, continuous with that of the conjunctiva; the anterior limiting layer; the substantia propria; the posterior limiting layer; and the endothelium of the anterior chamber, called the keratoderma.

Cortical cataract: A type of cataract in which there is progressive opacification of the outer shell of the lens.

Crystalline lens: A transparent biconvex cellular body lying between the iris and the vitreous. One of the refracting media of the eye, it consists of a soft outer part (cortical substance) with a denser central part (nucleus). The lens is surrounded by a fine membrane, the capsule.

Extracapsular cataract extraction (ECCE) surgery: Surgical removal of the cataractous lens from the lens capsule without concurrent removal of the lens capsule. In this procedure, the anterior capsule of the lens is removed, the nucleus of the cataract is expressed, and the residual cortical material is aspirated from the eye. The posterior capsule is left intact, and an intraocular lens is placed in the capsular bag, which restores vision.

Functional impairment: When applied to cataracts, the degradation of a person's ability to function as he or she normally would if his or her vision were not impaired as a result of cataract.

Glare: In persons with cataracts, the bright, blurred visual perception of light under certain conditions of bright light. Glare in persons with cataract is caused by lens opacities that scatter light.

Glare tests: Tests that attempt to reproduce the symptom of glare in cataract patients and to quantify the amount of visual impairment it causes by comparing acuity with and without a bright light source directed by the eye. See glare.

Glaucoma: A condition in which the pressure of the fluid in the eye becomes so great that it damages the small internal blood vessels and/or optic nerve fibers, resulting in nerve fiber destruction and partial or complete loss of vision. Glaucoma is one of the most common major eye disorders in people over 60.

Intracapsular cataract surgery: A surgical technique for removing cataracts in which the whole lens in its capsule is extracted either by forceps or a cryoprobe to permit artificial lens implantation.

Intraocular lens (IOL): An artificial lens that is implanted into the eyes of patients who have had their cataracts surgically removed and designed to restore the lost focusing power of the removed natural lens.

Lens capsule (capsule lentis): The capsule enclosing the lens of the eye.

Lens opacity: A lack of transparency in the lens.

Mixed opacities: A combination of opacities involving different portions of the lens.

Nd:YAG capsulotomy: The most commonly used technique for treating posterior capsular opacification, usually referred to as YAG capsulotomy. With this technique, an Nd:YAG laser is used to make a hole in the central part of the lens to improve vision. Nd and YAG are abbreviations that stand for neodymium and yttrium aluminum garnet. See posterior capsular opacification.

Nonsurgical management: When applied to cataract patients, the use of nonsurgical techniques, such as education and counseling, to instruct patients on the effects and prognosis of their cataract condition. Also, the use of different prescription eyeglasses, magnifying lenses, visual aids, appropriate illumination, or pupillary dilation instead of surgery to enhance vision.

Nuclear sclerosis: A type of cataract in which the central portion, or nucleus, gradually increases in density and opacification.

Phacoemulsification (PE) cataract surgery: A surgical technique that is a modification of the extracapsular cataract extraction procedure whereby the nucleus of the cataract is fragmented by a probe oscillating at ultrasonic frequency and nuclear fragments are simultaneously aspirated from the eye. An intraocular lens is then implanted in the treated eye.

Posterior capsular opacification (PCO): An opacification, or clouding, of the posterior lens capsule that may be a natural consequence of modern cataract surgery. The most common treatment for this condition is the Nd:YAG capsulotomy. See lens capsule, Nd:YAG capsulotomy, YAG capsulotomy.

Potential vision tests: Subjective or objective tests designed to determine whether patients with obviously impaired vision have the potential to see well following cataract surgery. These tests attempt to ascertain whether the limiting factor to visual impairment is cataract rather than other pathology. Subjective tests include the superthreshold pinhole device, Maddox rod test, laser interferometer, and Guyton-Minkowski potential acuity meter. Electrophysiologic tests are objective tests in which the response to visual stimuli is measured electronically.

Preoperative medical tests: Tests used to assist in determining the patient's medical suitability for surgery.

Preoperative ophthalmologic tests: In cataract patients, various tests that have been used in an attempt to determine the effect of the cataract on visual function and assess the patient's visual needs in order to determine the most appropriate method of treatment or therapy. See contrast sensitivity tests, glare tests, potential vision tests, Snellen visual acuity test, specular photographic microscopy of the corneal endothelium.

Quality of life: The attributes, nature, and condition of one's life. In health care, the term is often used to describe individuals' perception of the degree of value or meaningfulness associated with how they are able to conduct their lives, especially as that conduct is affected by their medical or health status.

Retina: The innermost of the three tunics of the eyeball. It consists of three parts: pars optica-retinae, pars ciliaris, and pars iridica retinae.

Retinal detachment: Separation of the inner layers of the retina (neural retina) from the pigment epithelium.

Risk factors: Any acts, circumstances, or conditions that increase the probability of developing a disease or of experiencing an adverse effect.

Snellen visual acuity test: A standard method of measuring visual acuity used during vision tests. Snellen's chart, bearing rows of letters of standard, decreasing size, is set at a predetermined distance from the patient. One eye is covered and the patient reads as far down the chart as possible. The procedure is repeated for the second eye.

Specular photographic microscopy of the corneal endothelium: A research tool sometimes used to try to identify patients at risk for developing problems with their corneas as a result of cataract surgery. The

test is used to examine and count a certain type of cell on the back surface of the cornea.

Visual acuity: Sharpness (discrimination) of central vision, as opposed to peripheral vision. A person's visual acuity is measured during a vision test.

Visual function: The sensory functioning of the eye; how well or poorly a person can see.

Visual impairment: A decrease in visual function that is subjectively and/or objectively demonstrable. Any person may be considered visually impaired if the corrected distant visual acuity in the better eye is 20/80 or less or if visual fields are significantly restricted. See visual function.

YAG capsulotomy: The usual term for the most commonly used technique for treating posterior capsular opacification. See Nd:YAG capsulotomy.

Biosketches

Numerous individuals have contributed their time and efforts to the development of this guideline. Their intense efforts and support during the critical interactive process have been an integral part of the success of this document.

DENIS M. O'DAY, MD, FACS
(Panel Chair)
George Weeks Hale Professor and Chair
Department of Ophthalmology
Vanderbilt University School of Medicine

He is an ophthalmologist, the George Weeks Hale Professor of Ophthalmology, and Chairman of the Department of Ophthalmology at the Vanderbilt University School of Medicine in Nashville, Tennessee, and a Director on the American Board of Ophthalmology. He is a founding member and is now Chair of the Quality of Care Committee of the American Academy of Ophthalmology. He has been involved in the development of a series of clinical guidelines for ophthalmology and has authored over 150 articles and book chapters.

ANTHONY J. ADAMS, OD, PhD
Dean
School of Optometry
University of California

He is a Professor of Optometry at the University of California at Berkeley. He has been Chairman of the National Research Council Committee on Vision and President of the National Board of Optometry. In 1991, he was elected to the Council of the American Academy of Optometry. He has published over 200 papers on various aspects of visual disorders.

EDWIN H. CASSEM, MD, FACP
Chief of Psychiatry
Department of Psychiatry
Massachusetts General Hospital

He is Chief of Psychiatry at Massachusetts General Hospital, Boston, and an Associate Professor of Psychiatry, Harvard Medical School. A Jesuit priest, he has degrees in experimental psychology, philosophy, and theology. He has specialized for 25 years in psychiatric care of the medically ill and is Chairman of the Optimum Care Committee at Massachusetts General Hospital.

JOHN V. DONLON, Jr., MD
Acting Chairman
Department of Anesthesiology
Massachusetts Eye and Ear Infirmary

He is Chief of Anesthesia at the Massachusetts Eye and Ear Infirmary, Boston, and Associate Clinical Professor of Anesthesia, Harvard Medical School. He specializes in the clinical practice of anesthesia as it relates to the surgical care of patients with cataract. He has written extensively on this topic.

DONALD J. DOUGHMAN, MD, FACS
Professor
Department of Ophthalmology
University of Minnesota Hospital and Clinic

He is an ophthalmologist, specializing in the medical and surgical treatment of diseases of the anterior segment of the eye, including cataract. He is a Professor of Ophthalmology at the University of Minnesota in Minneapolis. He is a member of the AHCPR Cataract Patient Outcomes Research Team and has served on national committees involved with quality of care issues.

DAGMAR B. FRIEDMAN, MPH, LICSW
Consultant
Vision Rehabilitation Services
Massachusetts Eye and Ear Infirmary

She is a clinical social worker with a psychotherapy practice in the Boston area. She currently serves on the Commonwealth of Massachusetts Statutory Advisory Board for the Massachusetts Commission for the Blind. She has extensive experience reviewing, designing, and implementing programs in visual rehabilitation. She has worked with patients with functional impairment due to cataract for many years and has developed a preventive health program for older adults in a large senior citizen center. She also served on the national task force to develop guidelines and standards for low-vision services throughout the United States.

CATHERINE GLYNN-MILLEY, RN, CRNO
President
Specialty Nursing Agency, Inc.

She is a certified ophthalmic registered nurse. Since 1982, she has provided in-home ophthalmic nursing services for patients in Santa Clara County, California. She has extensive experience managing patients following cataract surgery. A quality assurance plan addressing cost effectiveness and efficient community health care issues is the framework for her program. She also coordinates a blindness prevention program for the same community.

HARRY L. KNOPF, MD
Associate Professor of Clinical Ophthalmology
Department of Ophthalmology and Visual Sciences
Washington University School of Medicine

He is an ophthalmologist in private practice in St. Louis, Missouri. He is an Associate Professor of Clinical Ophthalmology, Washington University School of Medicine, and has served on several peer-review committees, including the National Advisory Committee on Patient Outcomes Assessment Research Program, Cataract Surgery, for the Health Care Financing Administration, and the Anterior Segment panel for the American Academy of Ophthalmology. He has experience in guideline development in these settings.

ERNEST L. MAZZAFERRI, MD, FACP
Professor and Chairman
Department of Internal Medicine
Ohio State University College of Medicine

He is a practicing internist and Professor and Chairman of the Department of Internal Medicine and Professor of Physiology at Ohio State University. He is also Chairman of Internal Medicine at Ohio State University Hospitals and Clinics. He is the author of over 200 medical and scientific articles, abstracts, and books. He has broad experience writing clinical guidelines as a member of the American College of Physicians' subcommittees in this area.

STEPHEN A. OBSTBAUM, MD
Professor of Clinical Ophthalmology
Cornell University Medical School
Director
Department of Ophthalmology
Lenox Hill Hospital

He is Professor of Clinical Ophthalmology at the Cornell University Medical School and Director of the Department of Ophthalmology at the Lenox Hill Hospital in New York City. He is Past President of the American Society of Cataract and Refractive Surgery and Editor of the *Journal of Cataract and Refractive Surgery*. He serves on the Board of Directors for the American Academy of Ophthalmology and is a member of the panel for developing the *Preferred Practice Pattern* on Cataract Surgery.

CHARLES J. PAPPAS, OD
Director of Optometric Services
Bascom Palmer Eye Institute
University of Miami School of Medicine

He is the Director of Optometric Services at the Bascom Palmer Eye Institute, University of Miami School of Medicine, with academic, clinical, consultative, and administrative responsibilities. He is a member of the Florida and American Optometric Associations.

EVA N. SKINNER, RN
Consultant
Los Angeles, California

She is a public health nurse and has worked in the geriatric field since 1964. She is a member of the Board of Directors of the American Association for Retired Persons and is a board member of the Visiting Nurse Association of America and California Medical Review, Inc., a peer review organization for Medicare in California. She is Chair of the California Commission on Aging.

ALFRED SOMMER, MD, MHS
Dean
The Johns Hopkins University School of Hygiene and Public Health

He is an ophthalmologist, Dean and Professor of Epidemiology at The Johns Hopkins School of Hygiene and Public Health, and a Professor of Ophthalmology at the Wilmer Institute. He was Founding Chair of the American Academy of Ophthalmology's Quality of Care Committee, which published 12 practice guidelines. He is Co-Principal Investigator of the AHCPR Cataract Patient Outcomes Research Team.

ARLO C. TERRY, MD
Associate Clinical Professor of Ophthalmology
University of Texas

He is an ophthalmologist in private practice, specializing in medical and surgical treatment of diseases of the anterior segment of the eye, including cataract. He is also an Associate Professor of Ophthalmology at the University of Texas, San Antonio. A founding member of the American Academy of Ophthalmology Quality of Care Committee, he has been involved in the production of a series of clinical guidelines for ophthalmology, including cataract.

LINDA A. VADER, RN, CRNO
Certified Registered Nurse in Ophthalmology
University of Michigan Kellogg Eye Center

She is a certified registered nurse in ophthalmology, with 15 years experience as Head Nurse at the University of Michigan Kellogg Eye Center. She was Charter President of the National Certifying Board of Ophthalmic Registered Nurses and is the Immediate Past President of the American Society of Ophthalmic Registered Nurses.

JAMES R. WEBER, MD
Assistant Clinical Professor
Department of Family and Community Medicine
University of Arkansas

He is a family physician in private practice in Jacksonville, Arkansas, and Assistant Clinical Professor, Department of Family and Community Medicine, University of Arkansas. He is a member of the Board of Directors of the American Academy of Family Physicians and served on the Surgery Technical Consulting Committee to the Harvard School of Public Health Resource-Based Relative Value Study on physician reimbursement.

VON BEST WHITAKER, PhD, RN, C
Assistant Professor
School of Nursing
University of Texas Health Science Center

She is an Assistant Professor in the School of Nursing at the University of Texas Health Science Center at San Antonio. She has a Master of Science in Community Health Nursing and a Master of Arts in Psychology. She is Chair of the American Society of Ophthalmic Registered Nurses Research Committee, a member of the American Public Health Association, and a member of a number of national organizations involved in ophthalmic nursing.

IRA G. WONG, MD
Chief, Department of Ophthalmology
Kaiser Permanente Medical Center
Assistant Clinical Professor
University of California-San Francisco

He is a practicing ophthalmologist specializing in the medical and surgical treatment of diseases of the anterior segment of the eye. He is Chief of Ophthalmology for The Permanente Medical Group and the Kaiser Permanente Health Care Program in Northern California. He has served as a consultant to the Physicians Payment Review Commission and to the Health Care Financing Administration on a variety of cataract care issues.

Contributors [1]

Methodology Consultants

Kay Dickersin, PhD
University of Maryland
School of Medicine
Baltimore, Maryland

Earl P. Steinberg, MD, MPP
The Johns Hopkins School of Mecicine
Baltimore, Maryland

Consultants, Contributors, Peer Reviewers, and Pilot Reviewers

Richard L. Abbott, MD
Clinical Professor
Department of Ophthalmology
California Pacific Medical Center
San Francisco, California

Ingrid Adamsons, MD, MPH
Wilmer Eye Institute
The Johns Hopkins School of Medicine
Baltimore, Maryland

Paul C. Ajamian, OD, FAAO
Omni Eye Services of Atlanta
Atlanta, Georgia

Raymond A. Applegate, OD, PhD
Department of Ophthalmology
University of Texas Health Science Center at San Antonio
San Antonio, Texas

James V. Aquavella, MD
University of Rochester Medical Center
Rochester, New York

Ian L. Bailey, OD
School of Optometry
University of California, Berkeley
Berkeley, California

Hal D. Balyeat, MD
Dean A. McGee Eye Institute
Oklahoma City, Oklahoma

Ray M. Balyeat, MD
Eye Institute of Tulsa
Clinical Instructor
University of Oklahoma
College of Medicine-Tulsa
Tulsa, Oklahoma

George M. Bohigian, MD
Washington University School of Medicine
St. Louis, Missouri

William M. Bourne, MD
Mayo Clinic
Rochester, Minnesota

Maureen Brennan-Duggan, RN, BSN, CRNO
Eye Medical Clinic of Santa Clara Valley
San Jose, California

William E. Bruner, MD
Case Western Reserve University
School of Medicine
Cleveland, Ohio

[1]Being listed as a contributor does not necessarily imply endorsement of the guideline.

Emmett F. Carpel, MD
Department of Ophthalmology
University of Minnesota
Hennepin County Medical Center
Group Health, Inc.
Minneapolis, Minnesota

Chris Carpenter, MSW
Mid-Maine Medical Center
Waterville, Maine

Clark R. Cobble, MD
Danville Eye Center, Inc.
Danville, Virginia

Matthew E. Dangel, MD
Department of Ophthalmology
Ohio State University
Columbus, Ohio

Gordon H. DeFriese, PhD
Professor of Social Medicine, Epidemiology and Health Policy and Administration
Director, Cecil G. Sheps Center for Health Services Research
University of North Carolina at Chapel Hill
Chapel Hill, North Carolina

Robert C. Drews, MD
Professor of Clinical Ophthalmology
Washington University School of Medicine
St. Louis, Missouri

David A. Durfee, MD
Oregon Eye Care
Oregon City, Oregon

Peter Egbert, MD
Stanford University
Stanford, California

James H. Elliot, MD
Professor of Ophthalmology
Vanderbilt University School of Medicine
Nashville, Tennessee

Darrin P. Fleming
The Turner Eye Institute
San Leandro, California

Robert H. Friedman, MD
The University Hospital
Boston University Medical Center
Boston, Massachusetts

Lea Gamble, BA
American Academy of Ophthalmology
San Francisco, California

Susan C. Garratt, BA
Freelance Editor
Mill Valley, California

Stephen C. Gieser, MD, MPH
The Johns Hopkins School of Medicine
Baltimore, Maryland

Martha S. Gerrity, MD, MPH
Cecil G. Sheps Center for Health Services Research
University of North Carolina
Chapel Hill, North Carolina

Thomas C. Gettelfinger, MD
Clinical Associate Professor of Ophthalmology
University of Tennessee Center for Health Sciences
Memphis, Tennessee

Robert J. Glynn, PhD, ScD
Department of Medicine
Brigham and Women's Hospital
Boston, Massachusetts

Philip M. Gold, MD
American College of Physicians
Philadelphia, Pennsylvania

Kathryn Goldblum, RN, MSN, CRNO
Albuquerque, New Mexico

John D. Gottsch, MD
Associate Professor of Ophthalmology
Wilmer Eye Institute
The Johns Hopkins University
Baltimore, Maryland

David Hadorn, MD
RAND Corporation
Santa Monica, California

Lisa M. Herdelin, BBA
Department of Ophthalmology
Vanderbilt University Medical Center
Nashville, Tennessee

Roger Hernandez, MD
San Antonio, Texas

Patricia L. Hibbard, MD, PhD
Harvard Medical School and Massachusetts General Hospital
Boston, Massachusetts

Janet E. Huettig, MSW, LICSW
Massachusetts Eye and Ear Infirmary
Boston, Massachusetts

Anthony C. Jaspers, MD, FAAFP
American Academy of Family Physicians
Kansas City, Missouri

Jonathan C. Javitt, MD, MPH
Georgetown University Medical Center
Washington, DC

Karla J. Johns, MD
Vanderbilt University School of Medicine
Nashville, Tennessee

Paul R. Katz, MD
University of Rochester School of Medicine and Dentistry
Rochester, New York

Robert H. Kennedy, MD, MPH
University of Texas
Southwestern Medical Center
Dallas, Texas

Joanne Klopfer, OD, MPH
Dana Center for Preventive Ophthalmology
Wilmer Eye Institute
The Johns Hopkins University Hospital
Baltimore, Maryland

Douglas D. Koch, MD
Cullen Eye Institute
Baylor College of Medicine
Houston, Texas

Manus C. Kraff, MD
American Academy of Ophthalmology
Chicago, Illinois

Stephen S. Lane, MD
Associate Clinical Professor
University of Minnesota
Minneapolis, Minnesota

Roger H. S. Langston, MD, CM, FACS
Cleveland Clinic Foundation
Cleveland, Ohio

Thomas L. Lewis, OD, PhD
Pennsylvania College of Optometry
Philadelphia, Pennsylvania

Thomas J. Liesegang, MD
Mayo Clinic Jacksonville
Jacksonville, Florida

Wilber W. Linville, OD, FAAO
Clinical Faculty
School of Optometry
University of California, Berkeley
Berkeley, California

Rajiv Luthra, MD, MPH
The Johns Hopkins School of Medicine
Baltimore, Maryland

Michael F. Marmor, MD
Stanford University
Stanford, California

James F. Martone, MD, MPH
ORBIS International
New York, New York

Samuel Masket, MD
Jules Stein Eye Institute
UCLA School of Medicine
Los Angeles, California

R. Michael Massanari, MD, MS
Henry Ford Medical Center
Case Western Reserve University
Detroit, Michigan

Alice Y. Matoba, MD
Houston Veterans Affairs Hospital
and Baylor College of Medicine
Houston, Texas

David Musch, PhD, MPH
University of Michigan
Departments of Ophthalmology and
Epidemiology
Ann Arbor, Michigan

Randall J. Olson, MD
University of Utah
School of Medicine
Salt Lake City, Utah

Carolyn M. Parrish, MD
Vanderbilt University School of
Medicine
Nashville, Tennessee

David F. Partlett, LLB, LLM, JJD
Vanderbilt University School of
Law
Nashville, Tennessee

John C. Perlmutter, MD
Assistant Professor of Clinical
Ophthalmology and Visual Sciences
Washington University School of
Medicine
St. Louis, Missouri

W. David Pool, OD
Illinois Optometric Association
Galva, Illinois

Neil R. Powe, MD, MPH, MBA
The Johns Hopkins School of
Medicine
Baltimore, Maryland

Dinah Reitman, MPS
Mt. Sinai School of Medicine
New York, New York

Claudia U. Richter, MD
Harvard Medical School
Boston, Massachusetts

Bridget Reilly, PhD
Vanderbilt University
Nashville, Tennessee

Gary S. Rubin, PhD
The Johns Hopkins University
School of Medicine
Baltimore, Maryland

Henry S. Sacks, PhD, MD
Mount Sinai School of Medicine
New York, New York

Oliver D. Schein, MD, MPH
The Johns Hopkins University
Baltimore, Maryland

Pamela S. Schremp, RN, MSN,
CRNO
University Hospitals of Cleveland
Case Western Reserve University
Cleveland, Ohio

Charles B. Slonim, MD, FACS
Clinical Assistant Professor
University of South Florida
College of Medicine
Tampa, Florida

Carol Standardi, RN, CRNO
W.K. Kellogg Eye Center
Department of Ophthalmology
University of Michigan
Ann Arbor, Michigan

John A. Stanley, MD
University of California
San Francisco, California

Walter J. Stark, MD
Wilmer Eye Institute
The Johns Hopkins Hospital
Baltimore, Maryland

Richard H. Stein, MD
Good Samaritan Hospital
Vincennes, Indiana

Gary M. Stephenson, MS
President, MED-WRITE
Sykesville, Maryland

Hunter R. Stokes, Sr., MD, FACS
Acting Chairman and Professor
Department of Ophthalmology
University of South Carolina School of Medicine
Columbia, South Carolina

Ellen Strahlman, MD, MHS
Merck, Sharpe and Dohme Research Laboratories
Blue Bell, Pennsylvania

Debra A. Street, MPH
Worthen Center for Eye Care Research
Georgetown University Medical Center
Washington, D.C.

Alan Sugar, MD
Kellogg Eye Center
University of Michigan
Ann Arbor, Michigan

Joel Sugar, MD
University of Illinois at Chicago
Department of Ophthalmology and Visual Science
Chicago, Illinois

Jeffrey Susman, MD
Vice-Chairperson
Department of Family Medicine
University of Nebraska Medical Center
Omaha, Nebraska

James M. Tielsch, PhD
The Johns Hopkins School of Medicine
Baltimore, Maryland

Peter S. Visendi, OD, FAAO
Assistant Clinical Professor
University of California, Berkeley
Berkeley, California

Jonathan P. Weiner, DrPH
The Johns Hopkins School of Public Health
Baltimore, Maryland

Sheila West, PhD
Associate Professor
Dana Center, Wilmer Eye Institute,
The Johns Hopkins University
Baltimore, Maryland

Charles E. Womack, MD
American Academy of Family Physicians
Oklahoma City, Oklahoma

Stephen K. Wong, MD
Specialist: Cataract/Corneal Surgery
Sacramento, California

Kenneth Zahl, MD
Assistant Professor of Clinical Anesthesiology
Columbia University
New York, New York

Agency for Health Care Policy and Research

Jean R. Slutsky, PA, MSPH

Lawrence E. Williams

Margaret K. Rutherford

Rose Calbert Findley, MUP

Harriett V. Bennett

National Library of Medicine

Ione Auston, MLS

Contract Agencies

Health Systems Research, Inc.
Washington, D.C.

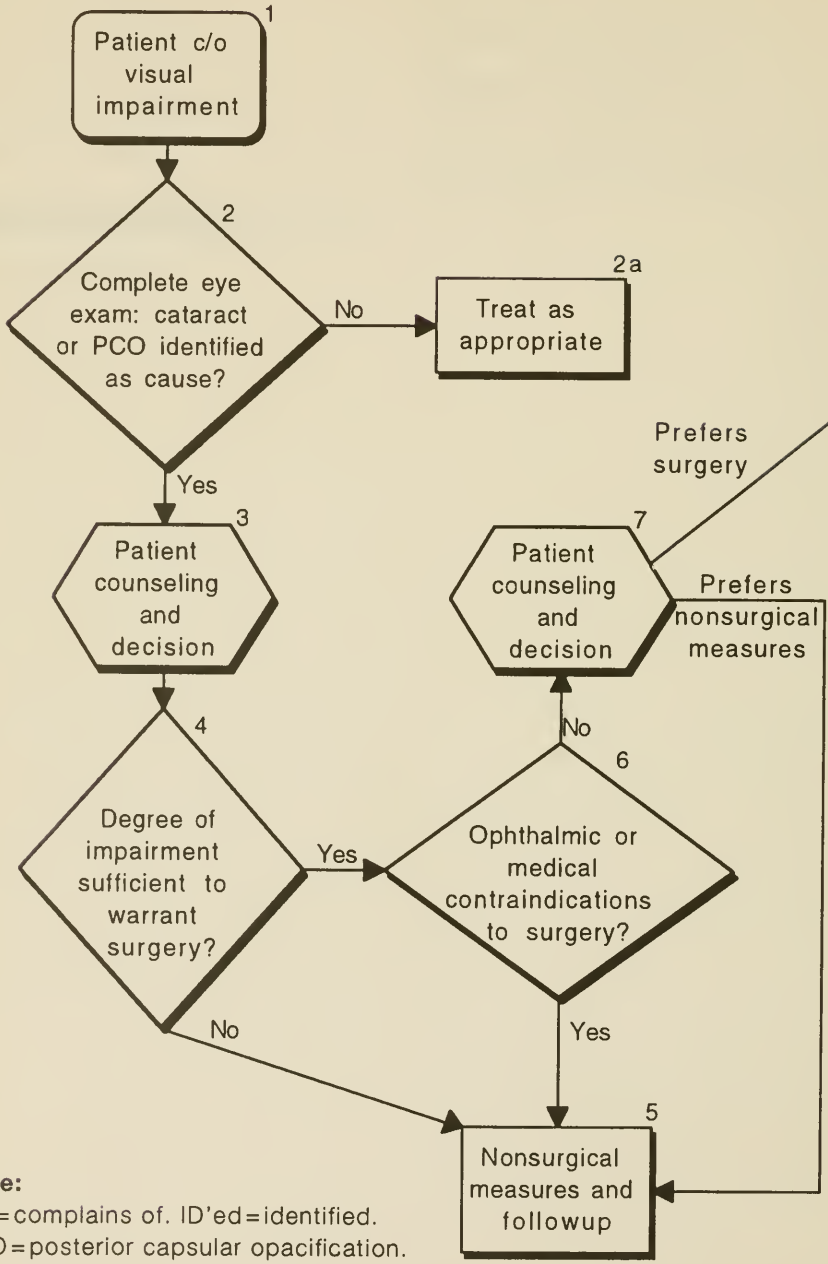
Mikalix and Company, Inc.
Waltham, Massachusetts

Moshman Associates, Inc.
Bethesda, Maryland

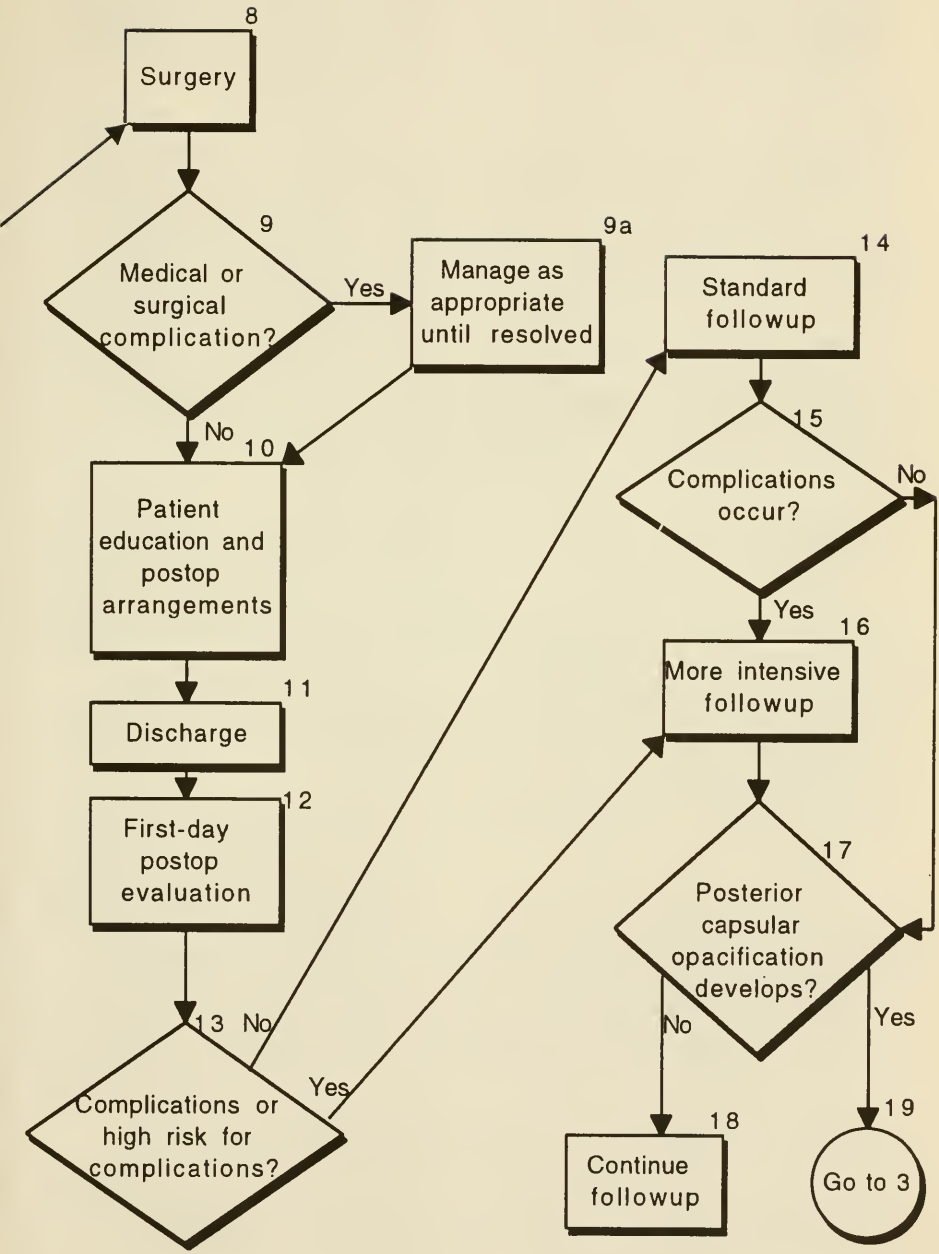
Washington Consulting Group, Inc.
Washington, D.C.

Attachments

Attachment 1. Algorithm



Note:
c/o = complains of. ID'ed = identified.
PCO = posterior capsular opacification.


8
Surgery
9
Medical or surgical complication?
Yes
9a
Manage as appropriate until resolved
No
10
Patient education and postop arrangements
11
Discharge
12
First-day postop evaluation
13
Complications or high risk for complications?
No
Yes
14
Standard followup
15
Complications occur?
No
Yes
16
More intensive followup
17
Posterior capsular opacification develops?
No
Yes
18
Continue followup
19
Go to 3

Annotation

1. Cataract evaluation and management should begin only when patients complain of a visual problem or impairment. Screening of asymptomatic patients for the presence of cataract is not appropriate. However, identifying an impairment in visual function during patient history and physical examination constitutes sound medical practice. Patients manifesting such an impairment should be referred for further evaluation and management, as appropriate.

2. Most elderly patients presenting with visual problems do not have a cataract that causes functional impairment. Refractive error, macular degeneration, and glaucoma are common alternative etiologies for visual impairment. For this reason, patients who present with new or recent visual impairment should receive a comprehensive eye examination. The management of patients with visual problems due to causes other than cataract is not addressed in this guideline.

   Patients with decreasing vision who have had cataract surgery commonly are found to have posterior capsular opacification (PCO). Decisionmaking concerning the management of this condition parallels that for patients with cataract. Therefore, these two conditions are considered together in this algorithm.

3. Once cataract or PCO has been identified as the cause of visual disability, patients should be counseled concerning the nature of the problem, its natural history, and the existence of both surgical and nonsurgical approaches to management. Patients should be advised that the principal factor that should guide decisionmaking with regard to surgery is the extent to which the cataract or PCO impairs their ability to function in their daily lives. The ophthalmologist should discuss with patients whether and how their visual problem affects their ability to work, care for themselves (or others), drive a car, read, or engage in hobbies and favorite activities.

   The degree of functional impairment reported by patients should be placed in the context of Snellen visual acuity, as obtained during the complete eye examination. As a general rule, the better the Snellen acuity is, the greater is the need for verification and documentation of functional disability. When best corrected visual acuity is 20/40 or better, the risk of surgery relative to its potential benefit becomes significant. Cataract surgery is often considered successful when acuity is restored to 20/40. Furthermore, this is the acuity required to obtain a driver's license in most States. For these reasons, patients with corrected visual acuity of 20/40 or better ordinarily should not be considered for surgery unless they report quite substantial functional impairment. These issues are discussed in Chapter 5.

   Formal or objective tests other than visual acuity are discussed in Chapter 4. The panel did not find evidence in the literature to support the use of any of these tests for deciding on the appropriateness of surgery.

4-5. Patients who report little or no functional impairment should generally be reassured that the cataract or PCO is not serious. Patients who complain of mild to moderate limitation in activities due to a visual problem, those whose corrected acuities are near 20/40, and those who do not yet wish to undergo surgery may be offered nonsurgical measures for improving visual function. Such measures include the use of strong bifocals or magnifying glasses and pupillary dilatation. At times, reassurance is all that is needed.

6. Patients who complain of visual functional disability and whose best corrected visual acuity is 20/50 or worse can be considered for surgery unless visual and medical contraindications exist. Patients with contraindications to surgery should be managed using nonsurgical measures. This management may consist of counseling and reassurance because, in patients with medical contraindications to surgery, there may be no nonsurgical measures that can change the patient's visual status.

7. Patients with significant functional and visual impairment due to cataract or PCO who have no contraindications to surgery should be counseled concerning the expected risks and benefits of surgery and alternatives to surgery. These outcomes are discussed in Chapter 5 for cataract surgery and Chapter 8 for YAG capsulotomy for PCO. Patients with a cataract should be informed of the likelihood of developing PCO following surgery and the possible need for an additional surgical procedure to correct this problem. PCO is discussed in detail in Chapter 8.

The most significant determinant of the potential outcome of surgery is the presence or absence of concomitant eye disease. Patients with preexisting glaucoma or corneal disease or with a history of previous eye surgery are at substantially greater risk for adverse outcomes than are patients without these factors. These issues are discussed in Chapter 5. In situations where concomitant eye disease could complicate the cataract procedure, patients might, after counseling, prefer to postpone surgery and should be managed using nonsurgical measures.

8. Technical considerations concerning the surgical removal of cataracts, including setting, choice of procedure, choice of anesthetic, monitoring, and arrangements for postoperative care, are discussed in Chapters 3 and 5. Correction of functionally significant PCO is generally performed using a YAG laser. This surgical procedure and appropriate followup activities are discussed in Chapter 8.

9. Following surgery, the ophthalmologist must assess whether any complications have arisen that would preclude safe discharge of the patient. These complications, which include hyphema, uncontrolled elevated intraocular pressure, unstable vital signs, nausea, and significant pain, are discussed in Chapter 6. Patients manifesting complications should be managed appropriately and should not be discharged until the complications have been resolved.

10-11. The ophthalmologist who performs the surgery has an obligation to educate the patient in the important areas of postoperative care prior to discharge, as discussed in Chapter 6. These areas include signs or symptoms of possible complications, eye protection, activity level permitted, medications, required visits, and details of access to emergency care. The patient should receive written followup instructions prior to discharge. In addition, the availability of an escort and of a suitable supportive environment should be assured prior to discharge.

12. The operating ophthalmologist should evaluate the patient the day following surgery. The content of this examination and the recommended schedule for additional followup visits are listed in Chapters 3 and 6. The findings on this first-day postoperative visit will in part determine the level of followup intensity required.

13. The ophthalmologist determines during the first-day postoperative visit whether complications have occurred. Complications, which are discussed in Chapter 5, include hyphema, infection, wound dehiscence, endophthalmitis, and severe pain. At this visit the ophthalmologist initiates postoperative treatment.

14. Patients who do not have complications and who are at low risk for developing complications should receive high-quality standard followup care, as discussed in Chapter 5. The ophthalmologist who performed the surgery is at all times responsible for the postoperative followup of his or her patient. In order to fulfill these responsibilities, the surgeon must examine the patient periodically until confident that the patient has fully recovered from surgery. The surgeon may, however, choose to delegate or involve other providers in some portion of the followup care. Use of this team approach to followup care is appropriate, provided that the patient is fully informed about the followup arrangements and understands how postoperative care is to be provided (including what to do in an emergency) and all those involved in followup care have demonstrated their ability to provide high-quality care.

15-16. Patients who are at high risk for complications and patients who develop complications either immediately postoperatively or during the course of standard followup care should receive more intensive followup care tailored to the particular problem or condition identified. In addition, high-risk patients should be counseled concerning the various rehabilitation modalities available, as described in Chapter 7.

17-19. Patients who have undergone cataract surgery are at relatively high risk for developing PCO. Patients who develop PCO should be counseled concerning the nature of this condition and available management options. The decisionmaking process described in this algorithm should again be followed, beginning at node #3.

Attachment 2. Literature Review Evidence: Contrast Sensitivity Testing

Reference: Hess and Woo, 1978.
Study Design: Case series.
Patients: 10 patients with uniocular senile cataract.
Type of Contrast Sensitivity Test: Vertical sine wave gratings of variable frequency and contrast.
Severity and Type of Cataract: • Severity: not given. • Type: cortical, nuclear cataracts included.
Type of Comorbid Ocular Pathology: None present.
Preoperative Visual Acuity: Not given; ratio of cataract to normal eye VA given.
Postoperative Visual Acuity or "Gold Standard": Gold standard: ratio of cataract to normal eye VA.
Findings: A single family of visual loss functions could not describe results. Correlation between ratio of cataract to normal eye VA and ratio of cataract to normal eye low spatial frequency abnormality was 0.1 ($p>0.2$).
Comments: Ratios may not be meaningful. Too few patients to adequately assess results.

Reference: Elliott, Gilchrist, and Whitaker, 1989.
Study Design: Case series.
Patients: • 18 patients, 39 eyes with cataracts; • 16 patients, 16 normal eyes.
Type of Contrast Sensitivity Test: • Contrast sensitivity described, not named. • Glare described, not named.
Severity and Type of Cataract: • Severity: graded 1 to 5 (Oxford cataract classification and grading system). • Type: nuclear, cortical, and subcapsular.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: LogMar VA—0.12 to 0.50.
Postoperative Visual Acuity or "Gold Standard": Gold standard: LogMar VA.
Findings: 1) For each type of cataract, as severity grade increased, CS significantly decreased for spatial frequencies ≥2 c/deg. 2) Moderate to high ($r=0.44$ to 1.0) correlations between CS and LogMar VA at ≥2 c/deg.
Comments: Confidence interval around correlation coefficients is wide because of small numbers in each subgroup. Subjects all had VA better than 20/200.

Reference: Maudgal, Stout, and vanBalen, 1988.
Study Design: Case series.
Patients: • 211 patients with ocular complaints; 24 of these had cataract. • 30 normals.
Type of Contrast Sensitivity Test: VCTS.
Severity and Type of Cataract: Not stated.
Type of Comorbid Ocular Pathology: Glaucoma (other, not specified).
Preoperative Visual Acuity: Not given.
Postoperative Visual Acuity or "Gold Standard": Gold standard: clinical exam.
Findings:

	Clinical Exam		
VCTS	Cataract	None	Total
Cataract	19	36	55
None	5	151	156
Total	24	187	211

Sensitivity = 19/24 = 79%
Specificity = 151/187 = 81%
Prevalence = 24/211 = 11%

Comments: VCTS evaluated in patients with ocular complaints.

Reference: Howes, Caelli, and Mitchell, 1982.
Study Design: Case series.
Patients: 55 patients: 42 diabetic; 3 macular disease; 10 normal.
Type of Contrast Sensitivity Test: CS described; not named.
Severity and Type of Cataract: • Severity grades: none (37 eyes), mild (35), and moderate (5). • Type: not given.
Type of Comorbid Ocular Pathology: Diabetic retinopathy.
Preoperative Visual Acuity: 20/20 or better.
Postoperative Visual Acuity or "Gold Standard": Gold standard: N/A.
Findings: CS appeared graphically to decrease with increasing severity of cataract and retinopathy.
Comments: No statistical tests done to determine if the lines graphed are significantly different from each other.

Reference: Koch, 1989.
Study Design: Case series.
Patients: • 41 cataract patients with VA 20/60 or better and complained of glare. • 10 patients without glare.
Type of Contrast Sensitivity Test: 1) Miller-Nadler glare tester. 2) Baylor visual function tester. 3) Stereo Optical glare tester. 4) VCTS.
Severity and Type of Cataract: • Severity: VA 20/60 or better. • Type: posterior subcapsular, nuclear.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: 20/60 or better.
Postoperative Visual Acuity or "Gold Standard": Gold standard: glare complaint.
Findings: • Correlation between contrast test results and glare complaints similar to contrast and Snellen VA. • False negative and false positives for contrast test were similar to those from Snellen VA when compared with patient complaints (gold standard).
Comments: Selection of patients (only those able to compare their glare complaints with the glare testing formats) might have inflated the correlations and decreased the false negative rate. Overall, Snellen performs similarly to, and is easier and less expensive than, contrast testing.

Reference: Lempert, Hopcroft, and Lempert, 1987.
Study Design: Case series.
Patients: • 68 eyes with PSC and VA 20/60 or better. • 146 eyes normal.
Type of Contrast Sensitivity Test: Computer controlled CS instrument, author's device.
Severity and Type of Cataract: • Severity: VA 20/60 or better. • Type: PSC.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: 20/60 or better.
Postoperative Visual Acuity or "Gold Standard": Gold standard: N/A.
Findings: Mean Snellen fraction denominators for the 146 normal eyes increased slightly (23 to 42) as contrast level decreased (95% to 3%). For the 68 PSC eyes, the denominator increased significantly (37 to 163) as contrast level decreased. VA decreased significantly for PSC but not for normals.
Comments: Comparison of CS between normals and PSC eyes. Not directly applicable to decisions about cataract surgery.

Reference: Singh, Cooper, Alder et al., 1981.
Study Design: Case series.
Patients: • 90 normal patients. • 27 cataract (48 eyes). • 25 glaucoma (45 eyes).
Type of Contrast Sensitivity Test: Arden gratings (plates 6 and 7).
Severity and Type of Cataract: • Severity: minimal. • Type: not given.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: Not given.

Postoperative Visual Acuity or "Gold Standard": Gold standard: N/A.
Findings: For cataract eyes, mean score was 14/5 ± 3 (all 48 eyes saw grating) on plate 6 and 13.7 ± 3 (33 eyes saw grating) on plate 7.
Comments: Study describes findings in normal, mild cataract, and glaucoma eyes. Not directly applicable to decisions about cataract surgery.

Reference: Skalka, 1981a.
Study Design: Case series.
Patients: 88 patients (122 eyes).
Type of Contrast Sensitivity Test: Arden Grating.
Severity and Type of Cataract: • Severity: early (VA 20/40 or better). • Type: PSC.
Type of Comorbid Ocular Pathology: None.
Preoperative Visual Acuity: 20/40 or better.
Postoperative Visual Acuity or "Gold Standard": Gold standard: N/A.
Findings: Tables give the ranges of Arden grating scores by age for patients with mild PSC and normals. Mean scores increase with increasing age (98.5 for 3d decade to 110.8 for 9th decade).
Comments: Although abstract claims that Arden scores correlate better than Snellen acuity with patients' subjective complaints, no data are present in the paper regarding patients' complaints.

Reference: Morris, Klett, Gieser et al., 1991.
Study Design: Case series.
Patients: 15 patients, 15 eyes.
Type of Contrast Sensitivity Test: Interferometric laser contrast sensitivity function.
Severity and Type of Cataract: • Severity: 20/70 to 20/200, N=11; worse than 20/200, N=4. • Type: mixed.
Type of Comorbid Ocular Pathology: Varied with patient.
Preoperative Visual Acuity: Isolated retina contrast sensitivity function.
Postoperative Visual Acuity or "Gold Standard": Postop optical plus retinal contrast sensitivity function.
Findings: In 10 of 15 patients, postop CSF was predicted accurately. 4 of 5 inaccurate predictions were in patients with VA <20/200.
Comments: 25% of cases lost to followup.

Reference: Elliott, Hurst, and Weatherill, 1990.
Study Design: Case series (cross-sectional).
Patients: 33 patients with cataract in at least 1 eye who were also about to enter an anticataract drug trial or to undergo surgery.
Type of Contrast Sensitivity Test: Pelli-Robson letter chart (both sides).
Severity and Type of Cataract: VA range = 6/4 to 6/36.
Type of Comorbid Ocular Pathology: Exclude patients with high intraocular pressure, retinal disease, diabetes, refractive error >±6DS, amblyopia, monophakia, abnormal neural function, poor general health.
Preoperative Visual Acuity: N/A.
Postoperative Visual Acuity or "Gold Standard": N/A.
Findings: Patients also completed questionnaire on vision-related functional disability. • Correlation (r) –0.65 between binocular CS score and patient responses on questions regarding mobility; mobility decreases as CS score increases. • r = –0.60 between binocular CS and near-vision responses. • r = –0.49 between binocular CS and discrimination responses.
Comments: • Moderately strong association between CS scores and patient perception of vision-related disability. • No statistical test performed to determine whether the difference in magnitude of correlations between CS and functional disability compared with those between VA and functional disability are statistically significant. • Cannot determine if differences in the

correlation coefficients are clinically significant even if they are statistically significant. • There are no postop data.

Note: CS = Contrast sensitivity. CSF = Contrast sensitivity function. PSC = Posterior subcapsular. VA = Visual acuity. VCTS = Vistech vision contrast test system.

Attachment 3. Literature Review Evidence: Glare Testing

Reference: Holladay, Prager, Trujillo et al., 1987.
Study Design: Case series.
Patients: 64 patients (14 normal, 50 cataract).
Type of Glare Test: Brightness acuity tester.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: Not given.
Visual Acuity Without Glare: Not given.
Postoperative Visual Acuity or "Gold Standard": Gold standard: outdoor VA (5,358 to 13,198 ft. candles).
Findings: No decrease in VA with the BAT or outdoor testing in normals. For cataract subjects, correlation between BAT and outdoor VA was r=0.84. Cataract patients had a 1- to 10-line reduction in VA.
Comments: No information regarding type/severity of cataract, complaints of glare, or sensitivity/specificity. No test-retest data given although abstract claims BAT reliable.

Reference: Hirsch, Nadler, and Miller, 1984a.
Study Design: Consecutive case series.
Patients: 52 cataract patients (84 eyes), 48 normal patients (81 eyes).
Type of Glare Test: Author's device.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: Not given.
Visual Acuity Without Glare: Mean = 20/48; range = 20/20 to 20/60.
Postoperative Visual Acuity or "Gold Standard": Gold standard: outdoor VA (≥2,000 ft. candles).
Findings: For cataract patients, correlation between glare scores and outdoor VA better for individuals facing sun (r^2=0.64) than those not facing sun (r^2=0.36). For normals, glare scores were "highly predictive" of outdoor acuity (r^2 not given).
Comments: Data difficult to decipher. Methods not standardized. Sun glare not standardized for glare test measurement.

Reference: Hirsch, Nadler, and Miller, 1984b.
Study Design: Case series.
Patients: 3 studies: N=46 (test-retest); N=5 (effect of refractive error on glare); N=126 (effect of contrast on glare).
Type of Glare Test: Described.
Severity and Type of Cataract: N=46 (13 normal eyes, 23 cataract eyes, 27 aphakic eyes). N=126 (35 normal; 94 cataract; 57 aphakic eyes).
Type of Comorbid Ocular Pathology: Not given.
Visual Acuity Without Glare: N/A.
Postoperative Visual Acuity or "Gold Standard": Gold standard: N/A.
Findings: Test-retest reliability varies with eye status: r=0.06, normal; r=0.95, cataract; r=0.54, aphakic. Glare scores change up to 5% with refractive error, and contrast sensitivity accounts for 10% of the variance in glare scores.
Comments: Reliability is highest in patients with cataract.

Reference: Hard, Abrahamsson, and Sjostrand, 1990.
Study Design: Case series.
Patients: N=16; 10 cataract patients who had glare problems, 3 normal, 3 others.
Type of Glare Test: Described.
Severity and Type of Cataract: • Severity: not given. • Type: nuclear, cortical, and PSC.
Type of Comorbid Ocular Pathology: None in cataract subjects.

Visual Acuity Without Glare: Better than 20/70.
Postoperative Visual Acuity or "Gold Standard": Gold standard: letter CS (without glare).
Findings: Test-retest reliability for: letter CS r=0.83, letter CS with glare r=0.92, VA r=0.89. With glare, cataract patients had a decreased letter CS independent of VA.
Comments: Tables and graphs difficult to interpret. Test-retest reliability good under conditions specified. However, study design would be stronger if individuals performing the test were not masked.

Reference: Elliott, Gilchrist, and Whitaker, 1989.
Study Design: Case series.
Patients: 18 subjects (39 eyes) with cataracts, 16 subjects (16 eyes) normal.
Type of Glare Test: • Contrast sensitivity described, not named. • Glare described, not named.
Severity and Type of Cataract: • Severity: graded 1-5 scale (Oxford cataract classification and grading system). • Type: nuclear, cortical, subcapsular.
Type of Comorbid Ocular Pathology: Not given.
Visual Acuity Without Glare: LogMar VA: 0.12 to 0.50.
Postoperative Visual Acuity or "Gold Standard": Gold standard: LogMar VA.
Findings: 1) High correlations between glare sensitivity and LogMar VA for cortical (r=1.0) and nuclear (r=0.77), but not PSC (r=0.12) cataracts. 2) Moderate to high (r=0.44 to 1.0) correlations between CS and LogMar VA at ≥2 c/deg (r=0.44 to 1.0).
Comments: Correlation coefficients may not be precise because of small numbers in each subgroup. Study results vary considerably with the type of cataract.

Reference: Abrahamsson and Sjostrand, 1986.
Study Design: Case series.
Patients: 18 normals, 34 subjects with PSC.
Type of Glare Test: Described.
Severity and Type of Cataract: • Severity: 0 to 100% opacification. • Type: PSC only.
Type of Comorbid Ocular Pathology: Not given.
Visual Acuity Without Glare: 20/20 to 20/200 (by figure).
Postoperative Visual Acuity or "Gold Standard": Gold standard: visual acuity.
Findings: Weak correlation between glare score and visual acuity, with a trend of increasing glare relating to decreasing VA (r not given).
Comments: 2 methods used to calculate glare scores gave different results. The average discrepancy in threshold contrast was used because of a "high reproducibility" of results, but no test-retest data were given.

Reference: Maltzman, Horan, and Rengel, 1988.
Study Design: Case series.
Patients: 114 eyes cataract, 20 eyes normal.
Type of Glare Test: Penlight.
Severity and Type of Cataract: • Severity: VA better than 20/200. • Type: not given.
Type of Comorbid Ocular Pathology: None.
Visual Acuity Without Glare: Better than 20/200.
Postoperative Visual Acuity or "Gold Standard": Gold standard: Snellen acuity.
Findings: Out of 40 eyes with VA 20/40 or better, 22 (55%) did not change with penlight and 2 (5%) had VA of 20/200. 16 out of 22 eyes with VA of 20/50 had VA of 20/200 or worse with penlight.
Comments: No mention was made of patients with glare complaints. Unclear whether patients with VA of 20/200 with the penlight complained of glare. Without an assessment of patients' functional disability and/or postop outcomes, these data do not directly address the ability of the penlight test to predict who will benefit from surgery.

Reference: Neumann, McCarty, Locke et al., 1988.
Study Design: Case series.
Patients: 48 cataract eyes.
Type of Glare Test: 1) Miller-Nadler. 2) Brightness acuity tester. 3) InnoMed true vision analyzer. 4) VisTech VCT8000. 5) Eye-Con 5.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: None.
Visual Acuity Without Glare: Not given.
Postoperative Visual Acuity or "Gold Standard": Gold standard: outdoor Snellen acuity.
Findings: The tests predicted outdoor acuity to within 1-line accuracy in 73% for BAT, 69% for TVA, 56% for VisTech, 47% for Miller-Nadler, and 15% for EyeCon. False positive and negative rates provided in the article.
Comments: Study highlights the problem of variability in glare tester's ability to predict outdoor acuity.

Reference: Koch, 1989.
Study Design: Case series.
Patients: 41 cataract subjects with VA 20/60 or better and complained of glare. 10 patients without glare.
Type of Glare Test: 1) Miller-Nadler glare tester; 2) Baylor visual function tester; 3) Stereo Optical glare tester; 4) Vistech vision contrast test system.
Severity and Type of Cataract: • Severity: acuity 20/60 or better. • Type: PSC, nuclear.
Type of Comorbid Ocular Pathology: Not given.
Visual Acuity Without Glare: 20/60 or better.
Postoperative Visual Acuity or "Gold Standard": Gold standard: 1) glare complaint; 2) severity and type of cataract.
Findings: Correlation between the 3 glare testers and patients' complaints ranged from r=0.39 to r=0.68. False positive rates (1–Sp) were 20% to 50% and false negative rates (1–Se) were 2% to 15%.
Comments: Selection of patients (only those able to compare their complaints with the glare testing formats) may bias the results and make the tests look better than they are (especially the correlations and false negative rates). With only moderate correlations with patients' complaints and a high false positive rate, these tests have questionable clinical utility.

Reference: Neumann, McCarty, Steedle et al., 1988b.
Study Design: Case series.
Patients: 78 patients (92 eyes with cataract and glare scores between 10% and 80%).
Type of Glare Test: Miller-Nadler glare tester.
Severity and Type of Cataract: • Severity: VA 20/20 to 20/300. • Type: pure nuclear, nuclear PSC, and other.
Type of Comorbid Ocular Pathology: Not given.
Visual Acuity Without Glare: 20/20 to 20/300 (81 eyes had VA 20/20 to 20/40 indoors and 33 had VA 20/20 to 20/40 outdoors).
Postoperative Visual Acuity or "Gold Standard": Gold standard: outdoor VA (8,000 to 11,900 ft. candles).
Findings: The Miller-Nadler predicted outdoor acuity was within 1 Snellen line of actual outdoor acuity for 47% of the eyes overall. For the 3 categories of cataract type, this percent ranged from 50% (nuclear), to 40% (nuclear and PSC), to 52% (other).
Comments: Predictions of outdoor acuity (within 1 line) are poor for all 3 types of cataract. No assessments of patients' complaints of glare and/or postoperative outcomes. As a result, this study does not directly address value of the test for preoperative decisionmaking.

Reference: Neumann, McCarty, Steedle et al., 1988a.
Study Design: Case series.
Patients: 78 subjects (106 cataractous eyes).
Type of Glare Test: Indoor Snellen acuity.

Severity and Type of Cataract: • Severity: VA 20/20 to 20/300. • Type: nuclear, nuclear and PSC, other.
Type of Comorbid Ocular Pathology: Not given.
Visual Acuity Without Glare: 20/20 to 20/300 (81 eyes had VA 20/20 to 20/40 indoors and 33 had VA 20/20 to 20/40 outdoors).
Postoperative Visual Acuity or "Gold Standard": Gold standard: outdoor VA (8,000 to 11,900 ft. candles).
Findings: 74 (70%) of eyes had outdoor VA ≥ 2 Snellen lines worse than indoor VA and 23 (22%) had outdoor VA ≥ 5 lines worse.
Comments: Authors compared indoor and outdoor Snellen acuity. There was no assessment of subjects' complaints of visual impairment or glare. Many of the eyes had VA of 20/40 or better indoors (76%) and outdoors (31%).

Reference: Prager, Urso, Holladay et al., 1989.
Study Design: Case series.
Patients: 51 normal subjects/eyes; 47 cataractous subjects/eyes.
Type of Glare Test: 1) Miller-Nadler glare tester; 2) brightness acuity tester.
Severity and Type of Cataract: • Severity: "minimal." • Type: not given.
Type of Comorbid Ocular Pathology: Not given.
Visual Acuity Without Glare: Mean for controls 20/20 (±2.11 SD); cataracts 20/43 (±18 SD).
Postoperative Visual Acuity or "Gold Standard": Gold standard: outdoor VA.
Findings: 1) Normal eyes had a mean VA of 20/20 indoors, outdoors, and with BAT. Miller-Nadler gave a VA mean of 20/24. 2) For cataract eyes, mean outdoor acuity was 20/45 (±17 SD). BAT overpredicted glare disability in 81% at high and 42% at medium settings. Miller-Nadler underpredicted in 62%.
Comments: 1) Randomization of indoor vs. outdoor testing and order of each instrument makes this a strong study design. It decreases the bias of a "carryover" or "training" effect from one test or setting to the other. 2) Use of only one eye from each patient is also a strength of this study. 3) Study demonstrates significant variability among glare testers.

Reference: Weiss, 1990.
Study Design: Case series.
Patients: 74 patients (118 eyes).
Type of Glare Test: 1) Glare situation described. 2) Mesopic vision situation described.
Severity and Type of Cataract: • Severity: VA 20/46 to 20/154. • Type: not given.
Type of Comorbid Ocular Pathology: Not given.
Visual Acuity Without Glare: 20/46 to 20/154.
Postoperative Visual Acuity or "Gold Standard": Postop vision: 20/22 to 20/42.
Findings: Statistically significant improvements occurred for all 3 acuity measures postop: standard landolt (0.28 preop vs. 0.69 postop), glare (0.06 vs 0.22), and mesopic (0.11 vs 0.34).
Comments: Comparisons were not made between preop glare (or mesopic vision) and postop Snellen acuity. Patients' complaints of glare were not given for preop and postop periods.

Reference: Masket, 1989.
Study Design: Case series.
Patients: 26 patients (30 eyes) with uncomplicated cataract surgery and postop acuity 20/20.
Type of Glare Test: Miller-Nadler.
Severity and Type of Cataract: • Severity: VA 20/30 to HM. • Type: nuclear, PSC, cortical.
Type of Comorbid Ocular Pathology: None.
Visual Acuity Without Glare: 20/30 to HM (mean 20/122).
Postoperative Visual Acuity or "Gold Standard": Postoperative VA: 20/20.
Findings: Mean glare score preop (55.2%, range 25 to 80%) was significantly different from postop mean (7.6%, range 2.5 to 15%).
Comments: 1) Selecting patients based on good surgical outcome (VA 20/20) may have biased results and limits generalizability of findings to the typical preoperative situation.
2) Glare scores improved after cataract removal. No indication as to whether patients had glare

symptoms and if these resolved postop. 3) Technician performing the glare testing was masked, making this a stronger study design.

Reference: Elliott, Hurst, and Weatherill, 1990.
Study Design: Case series (cross-sectional).
Patients: 33 patients with cataract in at least 1 eye.
Type of Glare Test: Mentor brightness acuity meter: 1) reduction in VA (GD_{VA}); 2) reduction in CS (GD_{CS}).
Severity and Type of Cataract: VA range = 6/4 to 6/36.
Type of Comorbid Ocular Pathology: Exclude patients with high intraocular pressure, retinal disease, refractive error >± 6.00, amblyopia, monophakia, abnormal neural function, poor general health.
Visual Acuity Without Glare: N/A.
Postoperative Visual Acuity or "Gold Standard": N/A.
Findings: Patients also completed questionnaire on vision-related functional disability. • Correlation (r) = 0.61 between worse eye GD_{VA} and near vision and r = 0.57 between worse eye GD_{VA} and discrimination. • r = 0.45 between worse eye GD_{CS} and discrimination. These correlations were slightly higher than those between VA and the same functional disabilities (r = 0.46 and 0.41, respectively).
Comments: Moderately strong association between GD_{VA} and near vision and between GD_{VA} and GD_{CS} and discrimination. • No statistical test performed to determine whether the differences in magnitude of correlations are statistically significant (e.g., between glare/functional disability vs. VA/functional disability). • Cannot determine if differences in the correlation coefficients are clinically significant even if they are statistically significant. • There are no postop data. • No data (scatter plots) or confidence intervals provided, just p values; so difficult to assess validity of analysis conclusions.

Reference: Levin, 1989.
Study Design: Case series.
Patients: 38 patients, good VA and with other visual symptoms.
Type of Glare Test: Innomed TVA—glare mode.
Severity and Type of Cataract: • Severity: VA 20/25 to 20/70. • Type: opalescent nuclear.
Type of Comorbid Ocular Pathology: None.
Visual Acuity Without Glare: 20/25 to 20/70.
Postoperative Visual Acuity or "Gold Standard": Postop VA: 20/15 to 20/30.
Findings: Preop contrast sensitivity (15%, glare mode) ranged from 20/80 to 20/2000. Postop CS (10% glare mode) ranged from 20/15 to 20/70 for all 38 patients.
Comments: 1) No report of whether patients' visual symptoms resolved postop. 2) All 38 patients had mild cataracts and no other ocular pathology, making it difficult to apply the results to a broader range of patients seen in practice.

Note: BAT = Brightness acuity tester. CS = Contrast sensitivity. GD_{CS} = Glare disability as measured by reduction in contrast sensitivity. GD_{VA} = Glare disability as measured by reduction in visual acuity. HM = Hand motion. PSC = Posterior subcapsular. SD = Standard deviation. Se = Sensitivity. 1–Se = False negative rate. Sp = Specificity. 1–Sp = False positive rate. TVA = True Vision Analyzer. VA = Visual acuity.

Attachment 4. Literature Review Evidence: Potential Vision Testing

Reference: Goldmann, Chrenkova, and Cornaro, 1980.
Study Design: Case series.
Patients: 41 patients.
Type of Potential Vision Test: Lotmar interferometer.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: Not given.
Postoperative Visual Acuity: Yes.
Findings: 1) Correlation between preop and postop IA was r=0.41; 2) correlation between preop IA and postop VA, r=0.54; test performs worse with dense cataract.
Comments: Performance is only fair in predicting postop vision.

Reference: Fukuhara, Oozato, Nojima et al., 1983.
Study Design: Cross-sectional.
Patients: N=52 eyes (12 patients with unilateral cataracts); no indication of number of patients.
Type of Potential Vision Test: VEP using laser speckled pattern.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: Not given for 12 eyes; 20/200 or worse for 40 eyes.
Postoperative Visual Acuity: 20/20 to CF.
Findings:

Prediction	Preop VA ≥20/40	Postop VA <20/40
Good	25	5
Poor	0	7
Total	25	12

Sensitivity = 25/25 = 1.0
Specificity = 7/12 = 0.58

Comments: For 12 unilateral cataract patients, equation predicting postop VA, using VEP, correlated highly (r=0.74) with postop VA. Predictive equation, if validated, useful only in patients with unilateral cataracts. Data suggest VEP may be sensitive for detecting patients with good postop VA. However, type of cataract not specified. Only by counting the number of eyes given in the tables can the sample size be discerned. Unclear how many pairs of eyes are from how many subjects.

Reference: Faulkner, 1983.
Study Design: 2 case series.
Patients: 137 cataract eyes.
Type of Potential Vision Test: Rodenstock retinometer.
Severity and Type of Cataract: • Severity: 20/70 to LP. •Type: 60 eyes—immature cataracts and normal maculas; 77 eyes—5 mature and 29 immature cataracts and other pathology.
Type of Comorbid Ocular Pathology: Macular scars; degeneration or holes; amblyopia; retinal atrophy; cystoid macular edema, etc.
Preoperative Visual Acuity: 20/70 to LP.
Postoperative Visual Acuity: 20/20 to CF.
Findings: 1) In the 60 eyes with immature cataracts and normal maculas, the retinometer predicted postop VA within 1 line in 53 (88%) and 2 lines in 7 (12%). 2) In the 77 eyes, 55 had other pathology. In 53 of the 55 (96%), the retinometer predicted better VA (by ≥ 2 lines) than was achieved postop. In 9 patients, the retinometer predicted worse VA than achieved (by ≥ 2 lines). These patients had mature cataracts or pupils were not dilated.
Comments: Presentation of data is unclear.

Reference: Essock, Williams, Enoch et al., 1984.
Study Design: Case series.
Patients: 15 patients.
Type of Potential Vision Test: Two-dot Vernier acuity.
Severity and Type of Cataract: • Severity: VA 20/25 to 20/1,000. • Type: mostly nuclear.
Type of Comorbid Ocular Pathology: None.
Preoperative Visual Acuity: 20/25 to 20/1,000.
Postoperative Visual Acuity: Postop VA: not given. • Gold standard: preop Snellen acuity and postop Vernier acuity.
Findings: Correlation between preop Vernier and preop Snellen acuity, r=0.83. Cataract removal decreased the thresholds, size of gap, and steepness of the curves for Vernier acuity.
Comments: No evidence given for whether preop Vernier acuity predicted postop acuity.

Reference: Enoch, Bedell, and Kaufman, 1979.
Study Design: Case series.
Patients: 61 patients (85 eyes) from 2d study.
Type of Potential Vision Test: Interferometer (laser).
Severity and Type of Cataract: • Severity: VA 20/20 to LP. • Type: not given.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: Landolt VA 20/20 to LP.
Postoperative Visual Acuity: 6/6 to CF.
Findings:

Prediction	Preop VA ≥6/12	Postop VA <6/12
≥6/12	19	0
<6/12	4	3
Total	23	3

Sensitivity = 19/23 = 0.83
Specificity = 3/3 = 1.0

Comments: Only 26 eyes of 21 patients had data given to calculate Se and Sp. Data on the other 40 patients were excluded, raising a question about possible selection bias (i.e., perhaps only those with good operative outcomes were included).

Reference: Dubey, Masani, and Shroff, 1983.
Study Design: Case series.
Patients: 100 cataract eyes.
Type of Potential Vision Test: 1) Maddox rod. 2) Retinometer. 3) 2-point discrimination.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: Not given. No pre, intra, or postop problems.
Preoperative Visual Acuity: Not given.
Postoperative Visual Acuity: 20/20 to 20/200.
Findings:

Maddox Rod Preop	Postop VA ≥20/30	Postop VA <20/30	Total
Grade I	80	1	81
Grade II	0	19	19
Total	80	20	100

Sensitivity = 80/80 = 1.0
Specificity = 19/20 = 0.95

Retinometer Preop	Postop VA ≥20/30	Postop VA <20/30	Total
≥6/9	18	0	18
<6/9	62	20	82
Total	80	20	100

Sensitivity = 18/80 = 0.22
Specificity = 20/20 = 1.0

Comments: 1) Only a few subjects gave consistent answers for 2-point discrimination.
2) Maddox rod is sensitive and specific for this limited group of patients.

Reference: Datiles, Edwards, Kaiser-Kupfer et al., 1987.
Study Design: Consecutive case series.
Patients: 27 patients (35 eyes).
Type of Potential Vision Test: PAM laser interferometer.
Severity and Type of Cataract: • Severity: a) mild to moderate cataracts, N=17 patients. b) severe cataract, N=15 patients. • Type: not given.
Type of Comorbid Ocular Pathology: a) Myopia, diabetes, retinal diseases. b) Myopia.
Preoperative Visual Acuity: a) 20/60 to CF at 18 inches. b) CF or worse.
Postoperative Visual Acuity: a) All patients were 20/20 or better. b) All patients were 20/30 or better.
Findings: a) PAM—16/17 patients with mild to moderate cataracts were correctly predicted to be 20/40 or better (sensitivity = 0.94). b) PAM—5/15 severe cataract patients were predicted correctly to be 20/40 or better (sensitivity = 0.33). The other 10 were predicted to be worse than 20/40 and all turned out to be 20/30 or better (false negative rate = 0.67). Laser—8/15 were correctly predicted to do well. 7/15 were wrongly predicted to have bad outcome (false negative rate = 0.47).
Comments: a) For patients with mild/moderate cataract and no comorbidity, PAM correctly predicted good outcome. No data about patients predicted to have poor outcome show good outcomes. Laser results are similar to PAM. b) Patients predicted to do well did well. For patients who were predicted to do poorly, test was correct only 1 out of 3 times (i.e., high false negative rate). Both instruments do well when there is mild/moderate cataract and there is no comorbidity; did not do well when patients had severe cataract.

Reference: Cruz and Adachi-Usami, 1989.
Study Design: Case series.
Patients: N=22, unilateral mature senile cataract with good VA in other eye and normal preop ERG. N=11, subnormal ERG preop.
Type of Potential Vision Test: Electroretinogram.
Severity and Type of Cataract: Mature cataract.
Type of Comorbid Ocular Pathology: Diabetic retinopathy; choroidal detachment or degeneration, branch vein occlusion in the 11 patients with subnormal ERGs.
Preoperative Visual Acuity: Not given.
Postoperative Visual Acuity: 20/20 to ≥20/50.
Findings:

ERG	Postop VA >20/20	Postop VA <20/50	Total
Normal	22	0	22
Subnormal	3	10	13
Total	25	10	35

Sensitivity = 22/25 = 0.88
Specificity = 10/10 = 1.0
Prevalence of good outcome = 71%

Comments: Highly selected group of patients (33 out of 153) with no indication that the study was prospective. Significant bias in the Se and Sp likely given selection of patients and lack of masking.

Reference: Cohen, 1976.
Study Design: Case series.
Patients: 163 eyes.
Type of Potential Vision Test: Interferometer (laser).
Severity and Type of Cataract: • Severity: VA 20/50 to LP. • Type: not given.
Type of Comorbid Ocular Pathology: 28 eyes had macular degeneration, diabetic retinopathy, chorioretinal degeneration, sarcoid, etc.
Preoperative Visual Acuity: 20/50 to LP.
Postoperative Visual Acuity: 20/25 to LP.

Findings: Postop VA was within 1 line of predicted acuity for 86% of eyes (140/163).

PA	Postop VA ≥20/50	Postop VA <20/50
≥20/50	122	3
<20/50	23	15
Total	145	18

Sensitivity = 122/145 = 0.84
Specificity = 15/18 = 0.83
Prevalence of good outcomes = 89%.

Comments: Test was correct 98% of the time when it predicted a good outcome but only 39% of the time when it predicted a bad outcome.

Reference: Minkowski, Palese, and Guyton, 1983.
Study Design: Case series.
Patients: 59 patients, 66 eyes with cataract (and strong suspicion of posterior pole disease for 35 eyes).
Type of Potential Vision Test: Potential acuity meter.
Severity and Type of Cataract: • Severity: not given. • Type: not given.
Type of Comorbid Ocular Pathology: Senile macular degeneration (20), high myopia (7), glaucoma (5), other (8).
Preoperative Visual Acuity: 20/50 to CF 1 foot.
Postoperative Visual Acuity: --

Findings:

PAM	≥20/40	<20/40	Total
≥20/40	38	2	40
<20/40	6	5	11
Total	44	7	51

Sensitivity = 38/44 = 0.86
Specificity = 5/7 = 0.71
Prevalence of good outcomes = 86%

Comments: 1) 15 eyes were excluded from the analysis, making it difficult to know what sensitivity and specificity were in the original patient population. 2) Predicted postop visual acuity was less accurate for patients with dense cataracts (VA worse than 20/200).

Reference: Miris and Missotten, 1982.
Study Design: Case series.
Patients: 62 eyes.
Type of Potential Vision Test: 1) Blue field entoptoscope. 2) Color perception test (RG).
Severity and Type of Cataract: Congenital, traumatic, and senile cataracts.
Type of Comorbid Ocular Pathology: Myopic choroidal dystrophy, congenital glaucoma, amblyopia, etc. (N=6 eyes).
Preoperative Visual Acuity: 2/10 to LP.
Postoperative Visual Acuity: Range or individual acuities not given.

Findings:

BFE	Postop VA ≥6/9	Postop VA <6/9	Total
+	27	0	27
–	27	6	33
Total	54	6	60

Sensitivity = 27/54 = 0.5
Specificity = 6/6 = 1.0
Prevalence of good outcomes = 90%

RG	Postop VA ≥7/10	Postop VA <7/10	Total
+	50	4	54
–	4	2	6
Total	54	6	60

Sensitivity = 50/54 = 0.93
Specificity = 2/6 = 0.33

Comments: BFE is not sensitive in detecting good outcomes in a group of patients with a 90% prevalence of good outcomes. RG test is sensitive but not specific. Neither test seems to perform well when cataract is dense (HM or worse).

Reference: Murphy, 1983.
Study Design: Case series.
Patients: 101 eyes cataract.
Type of Potential Vision Test: Blue field entoptoscope.
Severity and Type of Cataract: • Severity: 20/60 to LP. • Type: PSC, nuclear, cortical.
Type of Comorbid Ocular Pathology: Senile macular degeneration, diabetic maculopathy, optic atrophy, macular pucker.
Preoperative Visual Acuity: 20/60 to LP.
Postoperative Visual Acuity: 20/20 to CF.
Findings:

BFE	Postop VA ≥20/40	Postop VA <20/40	Total
+	77	5	82
–	17	2	19
Total	94	7	101

Sensitivity = 77/94 = 0.82
Specificity = 2/7 = 0.28
(assuming data are complete)

Comments: 1) BFE results depend on type and severity of cataract. 2) BFE performs poorly in patients with dense cataracts. 3) Using consecutive cases vs. selected cases makes this a stronger study design.

Reference: Sinclair, Loebl, and Riva, 1979.
Study Design: Consecutive case series.
Patients: N=154 patients (only reported on 136 eyes).
Type of Potential Vision Test: 1) BFE. 2) 2-light discriminator. 3) Color perception. 4) Purkinje vascular entoptic phenomenon.
Severity and Type of Cataract: • Severity: 20/70 to LP. • Type: not given.
Type of Comorbid Ocular Pathology: Macular degeneration, diabetes, myopia, retinal disease.
Preoperative Visual Acuity: 20/70 to LP.
Postoperative Visual Acuity: 20/40 or better N=118. 20/50 or worse N=18.
Findings:

BFE: Strong Light	Postop Macular Function (+)	Postop Macular Function (–)	Total
+	48	1	49
–	3	9	12
Total	51	10	61

Sensitivity = 48/51 = 0.94
Specificity = 9/10 = 0.90
Of the patients who turned out to have poor macular function (N=10), the blue field test identified 75% (weak light) to 90% (strong light).

Comments: In patients with good macular function, all the tests were good predictors of good postop outcome. In patients with poor macular function, BFE was best of the tests. BFE test was fairly good among the patients for whom results were reported. However, 25% of patients predicted to have poor postop macular function have good macular function. BFE results were not reported for 50% of eyes in the study. This may have biased the results.

Reference: Skalka, 1981b.
Study Design: Case series.
Patients: 150 patients.
Type of Potential Vision Test: 1) Blue field entoptoscope. 2) Visually evoked responses.
Severity and Type of Cataract: • Severity: VA 20/20 to LP. • Type: not given.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: 20/50 to LP.

Postoperative Visual Acuity: 20/20 to LP.
Findings:

1) Preop VA 20/400 or better: BFE

	Postop VA ≥20/40	Postop VA <20/40	Total
+/– [1]	?	?	102
–	7	5	12
Total	?	?	114

Negative predictive value = 5/12 = 0.042.
[1] +/– refers to positive or equivocal results of BFE test.

2) Preop VA CF or worse: BFE

	Postop VA ≥20/40	Postop VA <20/40	Total
+/– [1]	?	?	11
–	18	7	25
Total	?	?	36

Negative predictive value = 7/25 = 0.28.
[1] +/– refers to positive or equivocal results of BFE test.

Comments: Data not presented. The predictive values are highly dependent on the prevalence of an outcome.

Reference: Tabbut and Lindstrom, 1986.
Study Design: Case series.
Patients: 100 eyes in 93 patients.
Type of Potential Vision Test: Laser interferometry.
Severity and Type of Cataract: Not clear.
Type of Comorbid Ocular Pathology: Good mix (glaucoma, corneal abnormality, macular degeneration, diabetic retinopathy, etc.).
Preoperative Visual Acuity: --
Postoperative Visual Acuity: Data presented in a confusing manner.
Findings: In patients with least dense cataract (good preop VA), prediction was very good.

Predicts Improvement	Postop Improvement	
	Yes	No
Yes	77	3
No	15	5
Total	92	8

Predicted
Sensitivity = 77/92 = 0.84.
Specificity = 5/8 = 0.62.
In patients with least dense cataract (good preop VA) prediction was very good.
Comments: Predictive accuracy was poor in patients who had dense cataract; tended to predict that patients would not do well postop but many did well. Accurate in patients with mild to moderate cataracts; predicted that they would all do well and they did well.

Reference: van Lith and Hekkert-Wiebenga, 1983.
Study Design: Case series.
Patients: 14 normal patients; 97 cataract eyes.
Type of Potential Vision Test: Visually evoked potentials.
Severity and Type of Cataract: • Severity: 20/20 to 20/200 visual acuity. • Type: not given.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: 20/20 to 20/200.
Postoperative Visual Acuity: • Postop VA: N/A. • Gold standard: N/A.
Findings: Testing parameters are given for percent contrast and size of pattern. Stimuli most useful in evaluating patients with cataracts that did not seem dense enough to explain the low visual acuity.
Comments: Only patients with normal vision after surgery were included in the study. This limits the clinical relevance and generalizability of the findings.

Reference: Whitaker and Deady, 1989.
Study Design: Case series.
Patients: 35 patients (35 eyes).
Type of Potential Vision Test: Displacement threshold acuity.
Severity and Type of Cataract: • Severity: graded 1 (mild) to 3 (severe). • Type: nuclear (15), PSC (8), cortical (3).
Type of Comorbid Ocular Pathology: None.
Preoperative Visual Acuity: 6/12 to HM.
Postoperative Visual Acuity: 6/5 to 6/15.
Findings: 1) Mild association between preop displacement thresholds and acuity levels (r=0.37). 2) Strong association between preop and postop displacement thresholds (r=0.67). 3) Insignificant (r not given) correlation between preop thresholds and postop acuity.
Comments: Patients with ocular pathology (N=11) were not included in the results, limiting the generalizability of the findings. The association between preop and postop thresholds does not indicate whether the test is useful in predicting postop acuity.

Reference: Vrijland and van Lith, 1983.
Study Design: Case series.
Patients: 203 cataractous eyes referred by ophthalmologists for testing.
Type of Potential Vision Test: 1) Electroretinogram. 2) Visually evoked responses.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: Not given.
Postoperative Visual Acuity: Not given.
Findings:

ERG	Postop VA ≥20/40	Postop VA <20/40	Total
75-100%	100	11	111
<75%	61	31	92
Total	161	42	203

Sensitivity = 100/161 = 0.62
Specificity = 31/42 = 0.74

VER	Postop VA ≥20/40	Postop VA <20/40	Total
>21 μV	16	0	16
≤21 μV	135	52	187
Total	151	52	203

Sensitivity = 16/151 = 0.1
Specificity = 52/55 = 1.0.

Comments: Data given in percentages (%). Raw numbers were calculated from the percentage. Highly selective group of patients (those referred for ERG—about 10% of patients with senile cataract) limits the applicability of the results. ERG (Sp=0.74) and VER (Se=1.0) are good at identifying those who will not have good postop VA.

Reference: Grignolo, Moscone, Sobrero et al., 1988.
Study Design: Case series.
Patients: 53 patients (7 excluded because lens too dense).
Type of Potential Vision Test: 1) Lotmar visometer. 2) Blue field entoptoscope.
Severity and Type of Cataract: • Severity: 1/10 to LP. • Type: not given.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: 1/10 to LP.
Postoperative Visual Acuity: Postop VA 1/10 to 4/50.
Findings: 7 patients did not have visometry because of dense cataracts.

BFE	Postop VA ≥5/6	Postop VA ≤4/10	Total
+	41	9	50
–	2	8	10
Total	43	17	60

Sensitivity = 41/43 = 0.95
Specificity = 8/17 = 0.47

Lotmar	Postop VA ≥5/10	Postop VA ≤4/10	Total
+	32	4	36
–	5	12	17
Total	37	16	53

Sensitivity = 32/37 = 0.86
Specificity = 12/16 = 0.75.

Comments: Both tests are often inaccurate in their prediction of postop VA.

Reference: Christenbury and McPherson, 1985.
Study Design: Case series.
Patients: 108 patients.
Type of Potential Vision Test: Potential acuity meter.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: 20/60 to 1/200.
Postoperative Visual Acuity: Not given.
Findings:

PAM	Postop VA >20/40	Postop VA <20/40	Total
>20/40	48	4	52
<20/40	?	?	40
Total	?	?	92

Positive predictive value = 48/52 = 0.92.
92 of 100 patients had postop VA within 1 line or better of predicted acuity.
8 patients had cataracts too dense for using the meter.

Comments: The article reports positive predictive values, which are highly dependent on the prevalence of good postop outcomes. Data regarding accuracy of prediction that postop outcome will be poor are not provided. Unable to use PAM in patients with dense cataracts.

Reference: Spurny, Zaldivar, Belcher et al., 1986.
Study Design: Case series.
Patients: 54 eyes in 50 patients. Only 39 of those related to cataract.
Type of Potential Vision Test: 1) Potential acuity meter. 2) Lotmar.
Severity and Type of Cataract: • Severity: VA 20/20 to CF. • Type: not given.
Type of Comorbid Ocular Pathology: Some had comorbidity; 12 had no comorbidity.
Preoperative Visual Acuity: 20/25 to 20/400. 20/40 to CF at 1 foot.
Postoperative Visual Acuity: N=12 had no disease other than cataract 20/20 to 20/80. Patients with comorbidity (N=27) had 20/20 to 20/200.
Findings: For all patients combined, sensitivity = 15/28 = 0.54, specificity = 11/12 = 0.92. Positive predictive value = 15/16 = 0.93. Negative predictive value = 11/24 = 0.45. Prevalence of good outcome = 70% (good outcome = postop VA ≤ 20/40).
Comments: When PAM predicted that a good outcome would occur, it tended to be correct. When it predicted a bad outcome, a good outcome occurred over 1/2 the time. Predictive values are highly dependent on the prevalence of a good outcome.

Reference: Halliday and Ross, 1983.
Study Design: Consecutive case series.
Patients: 50 patients with cataract.
Type of Potential Vision Test: Two interferometers: 1) Haag-Streit visometer; 2) Rodenstock retinometer.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: 12 patients suspected to have comorbid eye disease.
Preoperative Visual Acuity: Not given.
Postoperative Visual Acuity: 20/20 to CF.

Findings: For both interferometers, the achieved acuity was often quite different from the predicted acuity. Less than 45% of the eyes achieved the predicted acuity ±25%.
Rodenstock: sensitivity = 0.65, specificity = 0.43.
Haag-Streit: sensitivity = 0.72, specificity = 0.30.
Comments: Use of consecutive patients makes this a stronger study design than if selected patients had been used. Predictive accuracy of the tests is poor.

Reference: Miller, Graney, Elam et al., 1988.
Study Design: Case series.
Patients: 82 patients (82 eyes).
Type of Potential Vision Test: 1) Laser interferometer; 2) potential acuity meter; 3) clinical judgment of ophthalmologists on the result of the interferometer and PAM.
Severity and Type of Cataract: • Severity: median VA 20/100. • Type: not given.
Type of Comorbid Ocular Pathology: • 62/82 eyes had no comorbidity. • 20 eyes: corneal disease (5); retinal disease (10); or both (2). • 3 retinas not visualized.
Preoperative Visual Acuity: 20/20 to CF or worse. No data on distribution of preop VA.
Postoperative Visual Acuity: Distribution of postop VA not reported. Median VA was 20/40.
Findings: 1) 11% of eyes had same or worse VA postop. 2) Exact prediction occurred with: PAM—11%, laser—15%, and clinical judgment—15% of eyes (clinical judgment = PAM + laser + clinical judgment). 3) Accurate prediction within 1 line occurred with: PAM—26%, laser—27%, and clinical judgment—57% of eyes.
Comments: Ophthalmologist clinical judgment combined with the 2 potential vision tests was better than either of the 2 tests alone. When an ophthalmologist has information from both test results, she/he can predict correctly 1/2 the time. No data on how well ophthalmologist can predict without the results of the two potential vision tests. No data on sensitivity, specificity, or predictive values.

Reference: Graney, Applegate, Miller et al., 1990.
Study Design: Case series.
Patients: 36 patients aged 70 and over and diagnosed presurgery to have retinal disease.
Type of Potential Vision Test: Author's clinical index for patients with retinal disease.
Severity and Type of Cataract: • Severity: VA 0.13 ± 0.11. • Type: not given.
Type of Comorbid Ocular Pathology: All had retinal disease.
Preoperative Visual Acuity: 0.13 ± 0.11.
Postoperative Visual Acuity: 64% were worse than 20/40 postop.
Findings: 1) Combination of 3 clinical variables was a good predictor of surgical outcome (sensitivity = 0.83, specificity = 0.85). Of the patients who had successful surgeries (VA 20/40 or better), 83% were predicted to succeed by the index. 2) Everyday activities of daily living (ADLs) and mental status (SPMSQ) were evaluated. Only 4 of the 14 everyday activities could be assessed because patients were relatively independent. Traveling independently beyond walking distance and independent shopping improved. Mental status did not improve significantly.
Comments: 1) Only study to examine functional impairments. 2) Authors did univariate statistics on 15 variables without doing a correction for multiple comparisons. If done, only preop VA would reach statistical significance. For the logistic regression model, there were too few subjects for 5 variables. Thus, results may not be reproducible. The predictive model needs to be validated using a second sample of patients before being considered for clinical use.

Reference: Bernth-Petersen and Naeser, 1982.
Study Design: Case series.
Patients: 90 cataract patients.
Type of Potential Vision Test: Lotmar visometer.
Severity and Type of Cataract: • Severity: immature vs. mature. • Type: not given.
Type of Comorbid Ocular Pathology: Macular disease (14 patients).

Preoperative Visual Acuity: N/A.
Postoperative Visual Acuity: ≤2.0 to 1.20.
Findings:

Pre-IA	Postop VA <0.5 (poor)	Postop VA ≥0.5 (good)	Total
<0.5 (poor)	7	7	14
≥0.5 (good)	7	38	45
Total	14	45	59

Sensitivity = 7/14 = 0.5
Specificity = 38/45 = 0.84
24 (27%) patients could not see the fringes, thus only 66 patients remained in the study; however, 1 died and 6 had postop complications, leaving a total of 59.
Comments: • Predictive accuracy of the test was poor. • 27% of patients dropped out of study, introducing a possible selection bias and limiting the generalizability of the findings.

Reference: Goldstein, Jamara, Hecht et al., 1988.
Study Design: Consecutive case series.
Patients: 40 eyes; patients requested surgery.
Type of Potential Vision Test: 1) SITE IRAS hand-held interferometer; 2) Haag-Streit Lotmar visometer.
Severity and Type of Cataract: • Severity: 20/50 to LP. •Type: not given.
Type of Comorbid Ocular Pathology: 6 patients had photopsia, postop trauma, macular degeneration, or amblyopia.
Preoperative Visual Acuity: 20/50 or worse.
Postoperative Visual Acuity: 20/15 to CF 1 foot.
Findings:

1. SITE IRAS	Postop VA ≥20/40	Postop VA <20/40	Total
≤20/40	21	3	24
>20/40	6	2	8
Total	27	5	32

Sensitivity = 21/27 = 0.77
Specificity = 2/5 = 0.40

2. Haag-Streit	Postop VA ≥20/40	Postop VA <20/40	Total
≥20/40	21	4	25
<20/40	5	1	6
Total	26	5	31

Sensitivity = 21/26 = 0.77
Specificity = 1/5 = 0.20.
Comments: 1) 5 eyes removed from study to "reduce testing variability." Data missing on 4 other eyes with VA of CF 10 or worse. This introduces possible selection bias. 2) Both tests are poor predictors of postop VA. In only 57% and 43% of eyes did the tests predict within 2 lines of postop VA.

Reference: Graney, Applegate, Miller et al., 1988.
Study Design: Consecutive case series with explicit inclusion/exclusion criteria.
Patients: Training set (N=157). Testing set (N=96).
Type of Potential Vision Test: 1) Clinical index—age, Snellen, visual acuity, number of medications, frequency of reading newspaper. 2) Laser interferometer. 3) Potential acuity meter.
Severity and Type of Cataract: • Severity: not given. • Type: not given.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: Training: 0.2 ± 0.2. Testing: 0.2 ± 0.1.
Postoperative Visual Acuity: Training: 0.6 ± 0.2. Testing: 0.5 ± 0.2.
Findings: 1. Training set: Percentage of patients predicted within 1 line: a) CI, 72%; b) LI, 37%; c) PAM, 33%.

	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
CI	96%	23%	56%	88%
LI	43%	90%	95%	24%
PAM	50%	81%	93%	25%

2. Testing set: a) Clinical index—61% predicted within 1 line (sensitivity = 91%, specificity = 26%, positive predictive value = 60%, negative predictive value = 69%).

Comments: For clinical index there was a high false (positive) rate (i.e., predicted that patients would do well who did not do well). Accuracy of LI and PAM was low when they predicted a poor outcome.

Reference: Lischwe and Ide, 1988.
Study Design: Case series.
Patients: 56 patients (8 with capsular opacities).
Type of Potential Vision Test: Blue field entoptoscope. Slides with moving corpuscle.
Severity and Type of Cataract: • Severity: clear media. • Type: not given.
Type of Comorbid Ocular Pathology: Macular degeneration, diabetes, histoplasmosis, retinal vein occlusion.
Preoperative Visual Acuity: Not given.
Postoperative Visual Acuity: Not given (scattergram indicates 20/20 to LP).
Findings: For patients with 20/200 or better postop VA.

BFE	Postop VA ≥20/40	Postop VA <20/40	Total
Slide 4 or less	23	0	23
Slide 5 or greater	8	10	18
Total	31	10	41

Sensitivity = 23/31 = 0.74
Specificity = 10/10 = 1.0
Positive predictive value = 23/23 = 100%
Negative predictive value = 10/18 = 56%.

Comments: False positive and false negative rates were not calculated correctly. The paper reports positive and negative predictive values. 15 patients with preop VA worse than 20/200 were excluded and 8 patients with capsular opacities included. The predictive value of a positive was high and predictive value of negative was low, but generalizability of findings is questionable.

Reference: Severin and Severin, 1988b.
Study Design: Case series.
Patients: 186 patients (210 eyes).
Type of Potential Vision Test: Potential acuity meter.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: Macular degeneration.
Preoperative Visual Acuity: Yes.
Postoperative Visual Acuity: Yes.
Findings: • 26% of cases predicted VA precisely. • 78% of cases predicted VA within 2 lines. • Ability to predict final VA better in patients with mild to moderate cataracts. • 8/10 false positives (overly optimistic) had macular degeneration.
Comments: Not stated whether ARMD was determined a) in all or only some patients, b) with or without knowledge of PAM result, c) preop or postop.

Reference: Weinstein, 1977.
Study Design: Case series.
Patients: 52 cataract patients.
Type of Potential Vision Test: Visually evoked potentials.
Severity and Type of Cataract: • Severity: 20/70 to CF. • Type: Not given.
Type of Comorbid Ocular Pathology: Not given.

Preoperative Visual Acuity: 20/70 to CF.
Postoperative Visual Acuity: 20/15 to CF.
Findings:

VEP	Postop VA ≥20/50	Postop VA <20/50	Total
Normal	9	4	13
Abnormal	3	4	7
Total	12	8	20

Sensitivity = 9/12 = 0.75
Specificity = 4/8 = 0.5.
Comments: 34 of 52 of the subjects (65%) did not have postop data. Results presented for only 20 eyes. Predictive accuracy was low among patients for whom data are reported.

Reference: Ing, 1986.
Study Design: Case series.
Patients: 32 cataract patients, 33 eyes.
Type of Potential Vision Test: Potential acuity meter.
Severity and Type of Cataract: • Severity: mixed. • Type: mixed; dense cataracts excluded.
Type of Comorbid Ocular Pathology: 3 patients with moderately advanced dry atrophic macular degeneration.
Preoperative Visual Acuity: 20/50 to 20/300.
Postoperative Visual Acuity: No individual values given.
Findings: Unable to calculate sensitivity and specificity from data given. In 31 of 33 eyes, achieved acuity was within 2 lines of predicted acuity (off by 3 lines in the other 2). 3 eyes achieved less than the predicted acuity. PAM tended to underestimate rather than overestimate outcome.
Comments: Dense cataracts excluded. Patients selected over 16-month period—relatively long time period to obtain only 33 patients; possible that patient recruitment may have been selective.

Reference: Adams and Shock, 1986.
Study Design: Case series.
Patients: 101 cataract patients.
Type of Potential Vision Test: Flying Corpuscle Viewer (entoptic device).
Severity and Type of Cataract: Not stated.
Type of Comorbid Ocular Pathology: Cystoid macular edema (2 patients); macular pucker (1 patient); diabetic maculopathy (1 patient).
Preoperative Visual Acuity: Not given.
Postoperative Visual Acuity: "Good" (VA ≥20/40 at 6 months) or "poor."
Findings:

Device Predicted	Postop VA "Good"	Postop VA "Poor"
≥20/40	61	20
<20/40	4	18
Total	65	38

Sensitivity = 19/23 = 0.83
Specificity = 3/3 = 1.0.
Comments: No information on type or severity of cataract; no controls for case severity; operative procedures varied considerably; predictive accuracy is low.

Reference: Davis, Sherman, Bass et al., 1991.
Study Design: Case series.
Patients: 124 cataract patients undergoing surgery. 112 patients included in analyses.
Type of Potential Vision Test: Snellen visual acuity, potential acuity meter, laser interferometer, blue field entoptoscope, bright flash visually evoked potentials.
Severity and Type of Cataract: All types.
Type of Comorbid Ocular Pathology: 38 (34%) had macular, optic nerve, or optic pathway disease.
Preoperative Visual Acuity: 20/200 or lower.
Postoperative Visual Acuity: Average = 20/40.

Findings: • Neither PAM nor LI provide good prediction of VA improvement, especially for patients with preop VA worse than 20/200. Prediction better for mild to moderate cataracts. • Multiple regression analysis to predict postop VA using data from all tests performed better than any single test. • Snellen, VA, LI, and VEP better than PAM and BFE for prediction.
Comments: Presentation of data difficult to interpret. All graphical representations of correlation.

Reference: Morris, Klett, Gieser et al., 1991.
Study Design: Case series.
Patients: 15 patients, 15 eyes.
Type of Potential Vision Test: Laser interferometer, contrast sensitivity function.
Severity and Type of Cataract: • Severity: 20/70 to 20/200, N=11; worse than 20/200, N=4. • Type: mixed.
Type of Comorbid Ocular Pathology: Varied with patient.
Preoperative Visual Acuity: Isolated retina contrast sensitivity function.
Postoperative Visual Acuity: Optical-plus-retinal contrast sensitivity function.
Findings: In 11 of 15 patients, postop CSF was predicted accurately. 3 out of 4 inaccurate predictions were in patients with VA <20/200.
Comments: 25% of cases lost to followup.

Reference: Bryant, 1985.
Study Design: Case series.
Patients: 101 patients.
Type of Potential Vision Test: Lotmar interferometer.
Severity and Type of Cataract: • Severity: mixed. • Type: nuclear and posterior subcapsular.
Type of Comorbid Ocular Pathology: Macular disease.
Preoperative Visual Acuity: Yes.
Postoperative Visual Acuity: Yes.
Findings: 1) Normal macula (N=60): • 80% of cases within 2 lines of predicted VA; • 48% of cases predicted VA precisely. 2) Abnormal macula (N=41): • 66% within 2 lines (too optimistic in 44%, too pessimistic in 22%); • 34% precise; • the more severe the macular disease, the greater the likelihood of being too optimistic. 3) Overall (N=101): • ability to predict final VA better with better preop vision, unreliable prediction at 20/200 or less; • with increased density of cataract, prediction too pessimistic; no difference for PSC or nuclear.
Comments: Retrospective (i.e., postop) grading of macular disease limits conclusions that can be drawn.

Reference: Carpel and Henderson, 1986.
Study Design: Case series.
Patients: 100 patients.
Type of Potential Vision Test: Potential acuity meter.
Severity and Type of Cataract: • Severity: not given. • Type: nuclear sclerosis, posterior subcapsular, cortical, combination.
Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: Not given.
Postoperative Visual Acuity: Not given.
Findings: 1) PAM was not obtained in 5 cases where VA was CF or worse. 2) In 82 of 95 cases (86%), the PAM prediction was within 3 lines of postop acuity.
Comments: Within 3 lines of predicted is not a very accurate level of prediction, and this was achieved in only 86% of cases.

Reference: Enoch, Williams, Essock et al., 1985.
Study Design: Cross-sectional.
Patients: Not given. Impossible to determine total.
Type of Potential Vision Test: 1) Vernier acuity, 2) gap test, 3) perimetry test.
Severity and Type of Cataract: • Severity: not given. • Type: not given.

Type of Comorbid Ocular Pathology: Not given.
Preoperative Visual Acuity: 20/20 to 20/1000.
Postoperative Visual Acuity: Not given.
Findings: 1) Majority of graphs describe a single patient or 2 to 4 patients. 2) Preop Snellen acuity and optimum vernier acuity are strongly correlated (r=0.83).
Comments: Too few patients in any one analysis to draw conclusions. Little information about predicting postop acuity.

Reference: Baraldi, Enoch, and Raphael, 1986.
Study Design: Case series.
Patients: 10 patients.
Type of Potential Vision Test: Gap test using vernier acuity.
Severity and Type of Cataract: • Severity: 20/70 to 20/1000. • Type: posterior subcapsular.
Type of Comorbid Ocular Pathology: None.
Preoperative Visual Acuity: 20/700 to 20/1000.
Postoperative Visual Acuity: 20/25 or better.
Findings: Each graph includes only 1 or 2 patients.
Comments: Graphs for only 5 of the 10 patients are given. Too few patients to draw any firm conclusions.

Reference: Enoch, Williams, Essock et al., 1985.
Study Design: Case series.
Patients: 15 patients.
Type of Potential Vision Test: 1) Gap test (vernier acuity). 2) Perimetry test.
Severity and Type of Cataract: Not given.
Type of Comorbid Ocular Pathology: None.
Preoperative Visual Acuity: 20/25 to 20/1000.
Postoperative Visual Acuity: Not given.
Findings: No evaluation of predictive accuracy of test results.
Comments: This study is a description of the results given by these tests, not an evaluation of their ability to predict postop VA. Moreover, too few patients to draw any firm conclusions.

Reference: Angra and Pal, 1990.
Study Design: Case series.
Patients: • 20 phakic controls (no medical opacity). • 20 aphakic controls. • 20 grade I cataracts. • 20 grade II cataracts. • 20 grade III cataracts. • 20 grade III cataract surgery. • 20 grade IV cataract surgery.
Type of Potential Vision Test: Laser interferometer.
Severity and Type of Cataract: See grades I to IV (mildly diminished fundus to no red fundus glow visible).
Type of Comorbid Ocular Pathology: Not given. No patients with abnormal maculas included.
Preoperative Visual Acuity: 6/26 to 6/6 (grade III cataract surgery patients) only.
Postoperative Visual Acuity: Cannot tell.
Findings: For cataract patients receiving surgery, 35% of cases were predicted accurately; 50% were predicted to have lower VA than achieved, and 15% were predicted to have higher VA than achieved.
Comments: Patients dropped from analysis if they had preoperative or postoperative complications. No raw data provided. Definitions of "accurate," "lower," and "higher" predictions not provided. Difficult to interpret writeup.

Note: ARMD = Atrophic retinal macular degeneration. BFE = Blue field entoptoscope. CF = Count fingers. CI = Clinical index. CSF = Contrast sensitivity function. ERG = Electroretinogram. HM = Hand motion. IA = Interference visual acuity. LI = Laser interferometer. LP = Light perception. PA = Potential acuity. PAM = Potential acuity meter. PSC = Posterior subcapsular. RG = Retinogram. Se = Sensitivity. Sp = Specificity. VA = Visual acuity. VEP = Visually evoked potentials. VER = Visually evoked responses.

Attachment 5. Literature Review Evidence: Potential Vision and Macular Degeneration

Reference: Faulkner, 1983.
Number of Eyes With Macular Degeneration: 35.
Type of Macular Degeneration: 1) 29 eyes, macular degeneration not defined. 2) 2 eyes, geographic atrophy of pigment epithelium of macular. 3) 4 eyes, serous detachments of sensory epithelium of macular.
Type of Potential Vision Test: Rodenstock laser interferometer.
Findings: 1) When MD not defined, predicted to within 1 line of Snellen acuity in 26/27 eyes, predicted within 2 lines in 28/29. 2) For geographic atrophy of pigment epithelium of macular, postop VA poorer than predicted. 3) No data given for other eyes.
Comments: 1) Did not define macular degeneration. 2) No data given for geographic atrophy of pigment epithelium of macular.

Reference: Spurny, Zaldivar, Belcher et al., 1986.
Number of Eyes With Macular Degeneration: 10.
Type of Macular Degeneration: Not defined.
Type of Potential Vision Test: 1) Lotmar interferometer. 2) Potential acuity meter.
Findings: 1) Lotmar predicted better acuity than achieved in 6/10 eyes; worse than achieved in 2/10. 2) Potential acuity meter predicted better acuity than achieved in 1/10 eyes; worse than achieved in 8/10.
Comments: Neither instrument useful in patients with macular degeneration.

Reference: Bernth-Petersen and Naeser, 1982.
Number of Eyes With Macular Degeneration: 14.
Type of Macular Degeneration: Not defined.
Type of Potential Vision Test: Lotmar interferometer.
Findings: No data given.
Comments: Authors concluded instrument not useful in patients with macular degeneration.

Reference: Cohen, 1976.
Number of Eyes With Macular Degeneration: 14.
Type of Macular Degeneration: Macular degeneration identified preop, but not defined; 11/14 eyes had preop VA of CF or HM.
Type of Potential Vision Test: Laser interferometer.
Findings: Predicted visual acuity within 2 lines in 10/14 eyes.
Comments: Reasonably good predictor considering poor preop acuities.

Reference: Tabbut and Lindstrom, 1986.
Number of Eyes With Macular Degeneration: 5.
Type of Macular Degeneration: Not defined.
Type of Potential Vision Test: Laser interferometer.
Findings: Predicted better acuity than achieved in 3 patients. Predicted within 1 line in 2 patients.
Comments: Small number of eyes studied.

Reference: Halliday and Ross, 1983.
Number of Eyes With Macular Degeneration: 12.
Type of Macular Degeneration: Macular degeneration not specified; included with other eye disease.
Type of Potential Vision Test: Two interferometers: 1) Haag-Streit visometer, 2) Rodenstock retinometer.
Findings: No data specific to macular degeneration.
Comments: --

Reference: Goldstein, Jamara, Hecht et al., 1988.
Number of Eyes With Macular Degeneration: 3.
Type of Macular Degeneration: Not defined.
Type of Potential Vision Test: Two interferometers: 1) SITE IRAS hand-held, 2) Haag-Streit Lotmar visometer.
Findings: No data given.
Comments: Authors concluded neither instrument useful in patients with macular degeneration.

Reference: Minkowski, Palese, and Guyton, 1983.
Number of Eyes With Macular Degeneration: 20.
Type of Macular Degeneration: Age-related macular degeneration or drusen.
Type of Potential Vision Test: Potential acuity meter.
Findings: Results not reported separately for eyes with macular degeneration.
Comments: --

Reference: Severin and Severin, 1988b.
Number of Eyes With Macular Degeneration: Number of eyes with macular degeneration cannot be determined from paper. Total of 210 eyes of 186 consecutive patients.
Type of Macular Degeneration: Not defined.
Type of Potential Vision Test: Potential acuity meter.
Findings: 8/10 eyes incorrectly predicted to have good results had senile macular degeneration.
Comments: No information on how many eyes had senile macular degeneration in total population.

Reference: Ing, 1986.
Number of Eyes With Macular Degeneration: 3.
Type of Macular Degeneration: Moderately advanced dry atrophic macular degeneration.
Type of Potential Vision Test: Potential acuity meter.
Findings: Postop VA was predicted within 2 lines in all 3 patients.
Comments: --

Reference: Murphy, 1983.
Number of Eyes With Macular Degeneration: 3.
Type of Macular Degeneration: Not defined.
Type of Potential Vision Test: Blue field entoptoscope.
Findings: Prediction was correctly positive for one eye. No data on whether 2 negative predictions were correct.
Comments: --

Reference: Sinclair, Loebl, and Riva, 1979.
Number of Eyes With Macular Degeneration: 8.
Type of Macular Degeneration: 5 disciform; 3 atrophic.
Type of Potential Vision Test: Blue field entoptoscope.
Findings: Results for eyes with macular degeneration not analyzed separately.
Comments: --

Reference: Skalka, 1981b.
Number of Eyes With Macular Degeneration: 4.
Type of Macular Degeneration: Postop diagnosis.
Type of Potential Vision Test: Blue field entoptoscope.
Findings: All (4) patients had negative or equivocal test preop.
Comments: No analyses as to whether predictions correct.

Reference: Lischwe and Ide, 1988.
Number of Eyes With Macular Degeneration: 33.
Type of Macular Degeneration: Not defined.
Type of Potential Vision Test: Blue field entoptoscope.
Findings: 7/33 correctly predicted to have positive results.
Comments: --

Note: CF = Count fingers. HM = Hand motion. MD = Macular degeneration. VA = Visual acuity.

Attachment 6. Literature Review Evidence: Specular Microscopy

Reference: Azen, Hurt, Steel et al., 1983.
Study Design: Case series.
Study Population Number and Type: 70 eyes; 67 patients, mean age 73, range 51-95. All received preop specular microscopy.
Preoperative Specular Microscopy Measure: Cell count (mean ± SE).
Exposure/Intervention: Extracapsular cataract extraction and posterior chamber lens implant.
Findings: One patient with postop CD but no information on preop specular microscopy for that patient.
Comments: Gives no information related to sensitivity/specificity; does not relate preop specular microscopy results to postop clinical outcome; does not report distribution of preop specular microscopy results on patients with good clinical outcomes.

Reference: Bates, Cheng, and Hiorns, 1986.
Study Design: Substudy of randomized controlled trial.
Study Population Number and Type: 274 eyes; 268 patients, mean age 72, range 55 to 89; preop specular microscopy on 9 patients with CD, 117 patients without CD.
Preoperative Specular Microscopy Measure: Cell count (mean ± SD).
Exposure/Intervention: 1) Intracapsular cataract extraction and contact lens; 2) intracapsular cataract extraction and iris-supported lens implant; 3) extracapsular cataract extraction and iridocapsular lens implant.
Findings: There were 9 patients with postop CD; 117 without; no difference in mean preop cell count of the 2 groups.
Comments: Data do not permit estimation of sensitivity/specificity; findings suggest specular microscopy does not discriminate between patients who will vs. will not develop CD.

Reference: Bates and Cheng, 1988.
Study Design: Substudy of randomized controlled trial (same as Bates, Cheng, and Hiorns, 1986).
Study Population Number and Type: Same as Bates, Cheng, and Hiorns, 1986. Preop specular microscopy on 3 groups: 9 with CD, 7 with high cell loss, 15 normal controls.
Preoperative Specular Microscopy Measure: Cell morphology (numerous measures).
Exposure/Intervention: Same as Bates, Cheng, and Hiorns, 1986.
Findings: No statistically significant differences for any preop morphologic measure except mean area of smallest cell (greater in CD patients than in controls).
Comments: Data do not permit estimation of sensitivity and specificity; data suggest preop morphology cannot predict postop outcome, but sample size is too small to draw valid conclusions.

Reference: Stur, 1988.
Study Design: Case series.
Study Population Number and Type: 161 eyes; mean age 72; 2/3 women. 146 eyes had preop specular microscopy (including 3 patients excluded from main analysis).
Preoperative Specular Microscopy Measure: Cell count (mean ± SD). Cell morphology (numerous measures).
Exposure/Intervention: Intracapsular cataract extraction with anterior chamber lens implant.
Findings: 3 patients had postop CD; 2 had low preop cell counts; 1 had normal preop cell count (exact cell counts not given).
Comments: Data do not permit estimation of sensitivity and specificity; too few patients to draw valid conclusions.

Reference: Kraff, Sanders, and Lieberman, 1980.
Study Design: Nonrandomized controlled trial.
Study Population Number and Type: 1,027 patients; 564 with preop and postop specular microscopy; 300 more patients had preop but no postop specular microscopy.
Preoperative Specular Microscopy Measure: Cell count (mean ± SD).
Exposure/Intervention: 1) Intracapsular cataract extraction. 2) Anterior chamber phacoemulsification. 3) Posterior chamber phacoemulsification. 4) Cataract extraction with lens implant (with preop and postop specular microscopy).
Findings: 5 patients had postop CD. Of these, there were preop specular microscopy on 3; all 3 had abnormal preop specular microscopy (1 with uncountable cells), 1 had preop cell count less than 1,000/mm^2 but cornea remained clear.
Comments: Suggests cell count might be predeterminant of corneal decompensation, but too few patients with evaluable data to draw valid conclusions.

Reference: Rao, Aquavella, Goldberg et al., 1984.
Study Design: Case series.
Study Population Number and Type: 118 eyes; 102 patients, mean age 65.8, range 51-86. All patients had preop and postop specular microscopy.
Preoperative Specular Microscopy Measure: Cell count, cell morphology (mean and range).
Exposure/Intervention: Intraocular lens implant.
Findings: 40 eyes with postop CD and 78 without; no significant difference in cell count of the 2 groups; patients with CD had greater variation in preop cell area.
Comments: Data do not permit estimation of sensitivity and specificity; cell count not of value; morphology may be of value; lens used in study is no longer used because of high complication rate.

Reference: Bourne and Kaufman, 1976.
Study Design: Case series.
Study Population Number and Type: 16 patients (age 16 to 80). All had preop specular microscopy.
Preoperative Specular Microscopy Measure: Cell count for individual patients.
Exposure/Intervention: Intracapsular cataract extraction or phacoemulsification.
Findings: No patients had CD; 3 patients had low (abnormal) preop cell count (<1,500).
Comments: Small sample size; data suggest preop cell count has low specificity but give no information for sensitivity.

Reference: Irvine, Kratz, and O'Donnell, 1978.
Study Design: Case series.
Study Population Number and Type: 23 patients.
Preoperative Specular Microscopy Measure: Cell count for individual patients.
Exposure/Intervention: Intracapsular cataract extraction or phacoemulsification, lens implant in 14 of 23.
Findings: No patients had CD; all patients had normal preop specular microscopy.
Comments: Data suggest good specificity but followup only 2-3 weeks. Too small a sample to draw valid conclusions. No information for sensitivity analysis.

Note: CD = Corneal decompensation (e.g., bullous keratopathy, corneal edema).
SD = Standard deviation. SE = Standard error.

Attachment 7. Literature Review Evidence: Anesthesia

Reference: Karhunen and Orko, 1981.
Study Design: Randomized controlled trial.
Study Population: 150 female patients, age = 72±7.
Exposure/Intervention: Atropine (local), pethidine with/without droperidol (local), atropine (general), pethidine (general).
Outcome Measures: Nausea and vomiting.
Findings: Droperidol appeared to reduce nausea in early postop time periods, but only statistically significant between local group with droperidol and general group without.
Comments: Although this was a randomized trial, there were too many confounding variables (should have been 2x2 factorial design; general vs. local with and without droperidol). No discussion of type II error as possible reason for lack of differences in some analyses. Needs multivariate analysis because of possible effects of other analgesics given.

Reference: Redmond and Dallas, 1990.
Study Design: Clinical series—comparative study.
Study Population: 100 Caucasian patients, mean age = 76.6 (57 to 96 range), age and sex ratios equivalent.
Exposure/Intervention: Retrobulbar vs. nonretrobulbar (subconjunctival bupivicaine) anesthesia.
Outcome Measures: Visual acuity; astigmatism complications.
Findings: No statistically significant differences in improvement of visual acuity or postop astigmatism. Complications included vitreous loss (3 retro, 2 nonretro), iris prolapse (1 retro), 2 wound leaks (retro), 2 residual cortex (nonretro). Surgeon's opinion—retro caused more stress than nonretro.
Comments: Not a prospective randomized study. An unknown number of cases were excluded from analysis retrospectively. This could have been subject to bias. No discussion of type II error. No discussion of baseline differences in visual acuity or systemic disease.

Reference: Smith, 1990.
Study Design: Uncontrolled trial (pseudocontrol groups).
Study Population: 208 eyes (193 patients, 118 female, 75 male, mean age 70.5, range 46 to 90, SD 14.5). Main series, 165 patients (175 eyes); 26 patients (30 eyes).
Exposure/Intervention: Nonretrobulbar anesthesia. Pseudocontrols: 30 eyes (general anesthesia); 3 eyes (retrobulbar).
Outcome Measures: Visual acuity complications.
Findings: There were few complications with nonretrobulbar anesthesia: 1 had convulsive hand movement during surgery; vitreous loss in 3 eyes; 1 had pain. No vitreous loss in general anesthesia cases. No obvious differences in postop visual acuity in 3 groups of patients, but no statistical analysis was performed. Nonretrobulbar technique was considered acceptable.
Comments: Not designed as a controlled trial, but used two comparison groups as a reference. This was really a Phase I/II study and needs confirmation by a larger randomized controlled trial.

Reference: Whitsett, Balyeat, and McClure, 1990.
Study Design: Double-blind randomized controlled trial.
Study Population: 100 patients (no description).
Exposure/Intervention: Retrobulbar vs. peribulbar local anesthesia.
Outcome Measures: Anesthesia efficacy (globe akinesia, lid akinesia, globe anesthesia). Supplemental anesthesia. Complications.
Findings: No statistically significant differences between groups for any outcomes measured. "No serious or potentially catastrophic complications."

Comments: Although this was a prospective double-blind randomized controlled trial, there was no discussion of patient populations, pre/postop visual acuity, function, or astigmatism. No discussion of statistical methods used. They did acknowledge small sample size and possible bias because of unblinded observers.

Reference: Hamilton, Gimbel, and Strunin, 1988.
Study Design: Consecutive series 1/2/84 to 4/8/88. Block type chronologically assigned A through E.
Study Population: 12,000 patients; about 70% were ≥70 years old; female, male rates, 62:38.
Exposure/Intervention: Blocks: A) retrobulbar plus 7th nerve block (N=3,595); B) increased volume retrobulbar block (N=1,640); C) dual peribulbar block (2 intraorbital) (N=3,478); D) dual peribulbar block (1 intraorbital, 1 through upper eyelid) (N=2,226); E) custom block (peribulbar plus retro is necessary) (N=1,061).
Outcome Measures: 1) Block score. 2) Complications: • brain stem anesthesia; • other CNS spread; • spread to contralateral orbit; • moderate retrobulbar hemorrhage; • eyelid conjunctivitis and peribulbar ecchymoses; • extraocular muscle paresis; • shivering; • scleral perforation; • optic atrophy; • vasovagal problems; • "breakthrough" pain.
Findings: 1) Blocks A and B achieved best scores. 2) 6/3,595 Block A and 2/1,640 Block B patients had brain stem anesthesia; 2 and 3 patients, respectively, had other CNS spread. 3) 15/1,640 Block B patients had extraocular muscle paresis (compared with 4, 3, and 1 with blocks C, D, and E). 4) Shivering highest with Block E (0.64%). 5) Vasovagal problems ranged from 0.5 to 0.85%. 6) "Breakthrough" pain significantly greater with A and B compared with C, D, and E; A was significantly worse than B.
Comments: • Study not masked so classification of complications subject to bias. • Numbers of complications small in each group; statistical comparisons between groups difficult. • No data on visual outcome or relationship between complications and postop vision.
• Complications in chronologically "early" block methods: no way to differentiate between chronologic effect (learning cause) and anesthetic effect.

Reference: Backer, Tinker, Robertson et al., 1980.
Study Design: Case series (comparative).
Study Population: 1a) 288 ophthalmic operations (local anesthesia) with prior myocardial infarction (195 patients); 69% males; 90% >60 years of age; mean age 72 years; 18% had diabetes; 40% had angina. 1b) 26 additional operations (21 patients) had general anesthesia (prior myocardial infarction). 2) Other series of 587 nonophthalmic operations; 79% males; mean age=67 years; 21% had diabetes; 34% had angina.
Exposure/Intervention: 1a) Ophthalmic surgery under local anesthesia. 1b) Ophthalmic surgery under general anesthesia. 2) Nonophthalmic surgery under general or major regional anesthesia.
Outcome Measures: Complications (postop reinfarction).
Findings: • No postop reinfarctions among local/retrobulbar or general anesthesia ophthalmic operations. • 6.1% reinfarction rate in nonophthalmic surgery group. • 3.3% reinfarction rate when only procedures ≤2 hrs. are included; 3.6% when eliminating "risky" upper abdominal, thoracic, or greater vessel operations of ≥3 hrs.
Comments: All retrospective comparisons. Too few ophthalmic procedures under general anesthesia with prior myocardial infarctions to expect any reinfarctions. Comparison of ophthalmology surgery with other types is subject to many confounding variables. This question may be researched through a meta-analysis. Will need many prospective clinical trials to find enough reinfarctions to draw conclusions.

Reference: Meyers, 1979.
Study Design: Case series (comparative).
Study Population: Approximately 1,300 patients; mean age=68 years.
Exposure/Intervention: Intraocular surgery—300 patients with standby anesthesiologist, 1,000 patients without standby (both groups had retrobulbar block).
Outcome Measures: Complications.

Findings: Without standby: 5.6% complication rate (mostly life threatening); 13% complications in nonstandby group, but excluded patients with tachycardia who were taking anticholinergic medications. Authors claim standby group did better.
Comments: Needs validation through randomized controlled trial. No discussion of baseline differences other than similarities in age. Why were tachycardia patients excluded from analysis of standby group? No indication that standby group was superior.

Reference: Whittpen, Rapoza, Sternberg et al., 1986.
Study Design: Consecutive series; different surgeons.
Study Population: 3,123 patients requiring retrobulbar injections. Group 1 patients (N=2,235) had a variety of procedures including cataract surgery. All Group 2 patients (N=388) underwent retinal reattachment or vitrectomy. Serum values of 20 "control" patients (noncases) also used.
Exposure/Intervention: Group 1: 2% lidocaine + 0.75% bupivicaine + hyaluronidase. Group 2: 4% lidocaine + 0.75% bupivicaine + hyaluronidase. All patients received preop sedation.
Outcome Measures: Respiratory arrest.
Findings: 1) 2/2,235 Group 1 patients had respiratory arrest (p=0.003) vs. 7/888 Group 2 patients. 2) 4/7 Group 2 patients had diabetes mellitus. 3) No sign differences in age, sex between groups. 4) No increase in serum levels of lidocaine or bupivicaine in cases compared with 20 "control" patients.
Comments: • Patients in Groups 1 and 2 had different surgeries and may have had different comorbidities associated with risk of respiratory arrest. • Not clear if 20 "controls" were noncases from Groups 1 and 2. • Not specific to cataract patients. • Respiratory arrest not defined. • Retrobulbar injection not defined or carried out by same surgeons. Cannot differentiate between technique effect and anesthesia effect.

Reference: Weiss and Deichman, 1989.
Study Design: Single-blind randomized controlled trial (surgeon blinded).
Study Population: 79 patients, unknown characteristics.
Exposure/Intervention: Retrobulbar vs. periocular anesthesia.
Outcome Measures: Complications: supplemental anesthesia, chemosis.
Findings: Only 1 patient in retrobulbar group had complication (tachycardia). 8/39 vs. 11/39 in retrobulbar vs. periocular patients required supplemental anesthesia ($p>0.10$, not significant); less chemosis in retrobulbar group ($p<0.001$); otherwise, no statistically significant difference between groups.
Comments: No discussion of population characteristics or differences thereof. No consideration of type II error. No evaluation of pre/postop visual acuity, visual function, astigmatism.

Note: CNS = Central nervous system. SD = Standard deviation.

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